

US3222220 (Prod: Accel Research Site - Avail - ERN-PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 16:05:20

All time stamps listed in this document are displayed in GMT

US3222220

Form: Participant Creation

Data signed: (b) (4) 19 Feb 2021 22:18:04

Generated On: 09 Jun 2021 16:05:20

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[Participant ID](#)

US3222220

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

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US3222220

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 22:18:04

Generated On: 09 Jun 2021 16:05:20

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

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 19 Feb 2021 22:18:04

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|   |  |
|---|--|
| Date of Birth (MMM yyyy)                  | (b) (6) 1956   |
| Age                                       | 63   |
| Age Units                                 | YEARS  |
| Age (Derived)                             | 63   |
| Sex                                       | Female <input checked="" type="radio"/><br>Male <input type="radio"/>  |
| Ethnicity                                 | Hispanic or Latino <input type="radio"/><br>Not Hispanic or Latino <input checked="" type="radio"/><br>Not Reported <input type="radio"/><br>Unknown <input type="radio"/> |
| Race (Check All That Apply)               |  |
| White                                     | True   |
| Black                                     | False  |
| Asian                                     | False  |
| American Indian or Alaska Native          | False  |
| Native Hawaiian or other Pacific Islander | False  |
| Other                                     | False  |
| If race is Other, specify _____           |  |
| Unknown                                   | False  |
| Not reported                              | False  |

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 19 Feb 2021 22:18:04

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|   |  |
|---|--|
| Date of Informed Consent ( <i>dd MMM yyyy</i> ) | 19 AUG 2020  |
| Month and Year of Informed Consent (derived)    | AUG 2020   |
| Year of Informed Consent (derived)              | 2020   |
| Protocol Version                                | Amendment 1 <input type="radio"/><br>Amendment 2 <input checked="" type="radio"/><br>Amendment 3 <input type="radio"/><br>Amendment 4 <input type="radio"/><br>Amendment 5 <input type="radio"/> |
| Was participant enrolled in the study?          | Yes <input checked="" type="radio"/><br>No <input type="radio"/>   |
| If No, indicate reason for screen fail          | Withdrew Consent <input type="radio"/><br>Inclusion/Exclusion <input type="radio"/><br>Cohort Full <input type="radio"/><br>Other <input type="radio"/>  |
| If reason for screen fail is Other, specify     |  |
| Was this participant screened previously?       | Yes <input type="radio"/><br>No <input checked="" type="radio"/>   |
| If Yes, previous participant number             |  |
| Enrollment Trigger                              | 1  |

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 19 Feb 2021 22:18:04

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 19 Feb 2021 22:18:04

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 19 Feb 2021 22:18:04

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



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 19 Feb 2021 22:18:04

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

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 19 Feb 2021 22:18:04

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|   |  |
|---|--|
| Condition   | GERD   |
| Start date (dd MMM yyyy)                                | UN UNK 2019  |
| Start date completely unknown                           | False  |
| Condition ongoing at study entry                        | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) _____ |  |
| Stop date completely unknown                            | False  |
| Start Month and Year (derived)                          | JAN 2019   |
| Start Year (derived)                                    | 2019   |
| Stop Month and Year (derived)                           | _____  |
| Stop Year (derived)                                     | _____  |

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 22:18:04

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|   |                                      |
|---|--------------------------------------|
| Were vital signs assessed?                | Yes <input checked="" type="radio"/> |
|   | No <input type="radio"/>             |
| Date of assessment ( <i>dd MMM yyyy</i> ) | 19 AUG 2020                          |
| Time of assessment ( <i>00:00-23:59</i> ) | 11:30 (24 HR)                        |
| Vital Signs Date and Time (derived)       | 19 AUG 2020 11:30                    |
| Height ( <i>xxx.x</i> )                   | 165.1 cm                             |
| Weight ( <i>xxx.x</i> )                   | 54.4 kg                              |
| BMI ( <i>xxx.x</i> )                      | 19.95744 kg/m <sup>2</sup>           |
| BMI units                                 | KG/M2                                |
| Temperature ( <i>xxx.x</i> )              | ND - Not Done                        |
| Route of measurement                      | Oral <input type="radio"/>           |
|   | Axillary <input type="radio"/>       |
|   | Other <input type="radio"/>          |
| If Other, specify                         |                                      |
| Pulse ( <i>xxx</i> )                      | ND - Not Done                        |
| Pulse units                               | BPM                                  |
| Respiratory Rate ( <i>xxx</i> )           | ND - Not Done                        |
| Respiratory Rate units                    | BREATHS/MIN                          |
| Systolic Blood Pressure ( <i>xxx</i> )    | ND - Not Done                        |
| Systolic Blood Pressure units             | MMHG                                 |
| Diastolic Blood Pressure ( <i>xxx</i> )   | ND - Not Done                        |
| Diastolic Blood Pressure units            | MMHG                                 |
| Height (derived)                          |                                      |
| Weight (derived)                          |                                      |

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 22:18:04

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 19 Feb 2021 22:18:04

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Date of assessment (*dd MMM yyyy*) 19 AUG 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 True

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 22:18:04

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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** INDIGENT CARE.

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

**No Risk Identified** True

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 22:18:04

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|  |       |
|--|-------|
| <b>Resides in Multi-family dwelling</b> (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs) | False |
| <b>Resides in high density housing</b> (e.g., high rise apartments with shared entrances or elevators)                                       | False |
| <b>Resides in low density, multi-family setting without</b> (e.g., apartments complex without shared entrances or elevators, duplexes)       | False |
| <b>Resides in a single family home</b> (i.e., detached housing)  | False |
| <b>Other</b>   | False |
| <b>Specify</b>   |       |

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 22:18:04

Generated On: 09 Jun 2021 16:05:20

|   |   |
|---|---|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|   | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)  | 19 AUG 2020                             |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/>              |
|   | Clinic <input checked="" type="radio"/> |
| Folder OID  | VISIT1                                  |



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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 19 Feb 2021 22:18:04

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What was the date of randomization? (dd MMM yyyy) 19 AUG 2020

What was the participant's randomization number? 105763

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 19 Feb 2021 22:18:04

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

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 22:18:04

Generated On: 09 Jun 2021 16:05:20

|                                     |  |
|-------------------------------------|--|
| 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)    | 19 AUG 2020  |
| Time of assessment (00:00-23:59)    | 11:40 (24 HR)  |
| Vital Signs Date and Time (derived) | 19 AUG 2020 11:40  |
| Temperature (xxx.x)                 | 36.0 C   |
| 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)              | 18 breaths/min   |
| Respiratory Rate units              | BREATHS/MIN  |
| Systolic Blood Pressure (xxx)       | 140 mmHg   |
| Systolic Blood Pressure units       | MMHG   |
| Diastolic Blood Pressure (xxx)      | 90 mmHg  |
| Diastolic Blood Pressure units      | MMHG   |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 22:18:04

Generated On: 09 Jun 2021 16:05:20

|                                     |  |
|-------------------------------------|--|
| 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)    | 19 AUG 2020  |
| Time of assessment (00:00-23:59)    | 13:40 (24 HR)  |
| Vital Signs Date and Time (derived) | 19 AUG 2020 13:40  |
| Temperature (xxx.x)                 | 36.5 C   |
| Route of measurement                | Oral <input checked="" type="radio"/><br>Axillary <input type="radio"/><br>Other <input type="radio"/> |
| If Other, specify                   |  |
| Pulse (xxx)                         | 86 beats/min   |
| Pulse units                         | BPM  |
| Respiratory Rate (xxx)              | 16 breaths/min   |
| Respiratory Rate units              | BREATHS/MIN  |
| Systolic Blood Pressure (xxx)       | 114 mmHg   |
| Systolic Blood Pressure units       | MMHG   |
| Diastolic Blood Pressure (xxx)      | 80 mmHg  |
| Diastolic Blood Pressure units      | MMHG   |

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 22:18:04

Generated On: 09 Jun 2021 16:05:20

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 AUG 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 22:18:04

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Was study treatment given? Yes ☒ No ☐

If No, reason not given Participant declined due to Adverse Event ☐  
Physician withheld dose due to Adverse Event ☐  
Death ☐  
Lost To Follow-Up ☐  
Physician Decision ☐  
Pregnancy ☐  
Protocol Deviation ☐  
Study Terminated by Sponsor ☐  
Withdrawal of Consent by Participant ☐  
Confirmed COVID-19 ☐  
Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 19 AUG 2020

What was the treatment time? (00:00-23:59) 12:51 (24 HR)

Treatment Date and Time (derived) 19 AUG 2020 12:51

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 22:18:04

Generated On: 09 Jun 2021 16:05:20

|                                    |                                      |
|------------------------------------|--------------------------------------|
| Was the sample collected?          | Yes <input checked="" type="radio"/> |
|                                    | No <input type="radio"/>             |
| Collection date (dd MMM yyyy)      | 19 AUG 2020                          |
| Collection time (00:00-23:59)      | 12:45 (24 HR)                        |
| Collection date and time (derived) | 19 AUG 2020 12:45                    |

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 22:18:04

Generated On: 09 Jun 2021 16:05:20

|                               |                           |                                 |                                    |
|-------------------------------|---------------------------|---------------------------------|------------------------------------|
| Collection date (dd MMM yyyy) |                           |                                 | 19 AUG 2020                        |
| Lab Test                      | Was the sample collected? | Collection time (00:00 - 23:59) | Collection date and time (derived) |
| Nasopharyngeal Swab 1         | Yes                       | 12:46                           | 19 AUG 2020 12:46                  |
| Nasopharyngeal Swab 2         | No                        |                                 |                                    |



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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 22:18:04

Generated On: 09 Jun 2021 16:05:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:05:20

**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

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

19 AUG 2020 13:11

PC Close Date & Time

19 AUG 2020 15:41

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:05:20

**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 99.1 °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        | 19 AUG 2020 18:47 |
| PC Open Date & Time  | 19 AUG 2020 16:36 |
| PC Close Date & Time | 20 AUG 2020 11:59 |

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:05:20

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**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

---

Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

98.5 °F

---

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

Yes ☐

No ☒

---

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

---

PC Time Stamp

20 AUG 2020 21:41

---

PC Open Date & Time

20 AUG 2020 12:00

---

PC Close Date & Time

21 AUG 2020 11:59

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US3222220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:05:20

**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

99.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 AUG 2020 07:38

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3222220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:05:20

**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

98.7 °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

22 AUG 2020 20:55

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3222220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:05:20

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**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °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

24 AUG 2020 00:45

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3222220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:05:20

---

**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

98.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 AUG 2020 18:44

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59



US3222220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:05:20

**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

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

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3222220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:05:20

**TIMEPOINT**

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

19 AUG 2020 13:11

PC Close Date & Time

19 AUG 2020 15:41

US3222220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:05:20

**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

19 AUG 2020 18:48

PC Open Date & Time

19 AUG 2020 16:36

PC Close Date & Time

20 AUG 2020 11:59

US3222220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:05:20

**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

20 AUG 2020 21:42

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3222220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:05:20

**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

22 AUG 2020 07:41

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3222220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:05:20

**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

22 AUG 2020 20:56

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3222220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:05:20

**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

24 AUG 2020 00:46

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3222220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:05:20

**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

24 AUG 2020 18:44

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59



US3222220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:05:20

**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 ☐

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

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3222220

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:05:20

**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 ☐

US3222220

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:05:20

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

19 AUG 2020 13:11

PC Close Date & Time

19 AUG 2020 15:41

US3222220

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:05:20

**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 ☐

US3222220

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:05:20

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

No ☒

Yes ☐

|                      |                   |
|----------------------|-------------------|
| PC Time stamp        | 19 AUG 2020 18:49 |
| PC Open Date & Time  | 19 AUG 2020 16:36 |
| PC Close Date & Time | 20 AUG 2020 11:59 |

US3222220

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:05:20

**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 ☒

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EAB) (1725)

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US3222220

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:05:20

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 20 AUG 2020 21:43 |
| PC Open Date & Time          | 20 AUG 2020 12:00 |
| PC Close Date & Time         | 21 AUG 2020 11:59 |

US3222220

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:05:20

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  
EAB) (1725)

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US3222220

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:05:20

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 22 AUG 2020 07:41 |
| PC Open Date & Time          | 21 AUG 2020 12:00 |
| PC Close Date & Time         | 22 AUG 2020 11:59 |

US3222220

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:05:20

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 ☒

PRODUCTION RELEASE (v12.003

49 of 1781

EAB) (1725)

US3222220

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:05:20

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 22 AUG 2020 20:57 |
| PC Open Date & Time          | 22 AUG 2020 12:00 |
| PC Close Date & Time         | 23 AUG 2020 11:59 |

US3222220

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:05:20

**TIMEPOINT**

DAY 5

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3222220

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:05:20

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 24 AUG 2020 00:47 |
| PC Open Date & Time          | 23 AUG 2020 12:00 |
| PC Close Date & Time         | 24 AUG 2020 11:59 |

US3222220

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:05:20

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  
EAB) (1725)

53 of 1781

US3222220

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:05:20

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 24 AUG 2020 18:45 |
| PC Open Date & Time          | 24 AUG 2020 12:00 |
| PC Close Date & Time         | 25 AUG 2020 11:59 |

US3222220

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:05:20

**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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

55 of 1781



US3222220

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:05:20

Yes ☐

PC Time stamp

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3222220

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 22:18:04

Generated On: 09 Jun 2021 16:05:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3222220

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 22:18:04

Generated On: 09 Jun 2021 16:05:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222220

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 22:18:04

Generated On: 09 Jun 2021 16:05:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3222220

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 22:18:04

Generated On: 09 Jun 2021 16:05:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222220

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 22:18:04

Generated On: 09 Jun 2021 16:05:20

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*

US3222220

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 22:18:04

Generated On: 09 Jun 2021 16:05:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222220

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 22:18:04

Generated On: 09 Jun 2021 16:05:20

|   |   |
|---|---|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|   | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)  | 17 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                                  |



US3222220

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 22:18:04

Generated On: 09 Jun 2021 16:05:20

|                                     |   |
|-------------------------------------|---|
| 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)    | 17 SEP 2020                               |
| Time of assessment (00:00-23:59)    | 08:23 (24 HR)                             |
| Vital Signs Date and Time (derived) | 17 SEP 2020 08:23                         |
| Temperature (xxx.x)                 | 37.1 C                                    |
| Route of measurement                | Oral <input checked="" type="radio"/>     |
|                                     | Axillary <input type="radio"/>            |
|                                     | Other <input type="radio"/>               |
| If Other, specify                   |   |
| Pulse (xxx)                         | 81 beats/min                              |
| Pulse units                         | BPM                                       |
| Respiratory Rate (xxx)              | 17 breaths/min                            |
| Respiratory Rate units              | BREATHS/MIN                               |
| Systolic Blood Pressure (xxx)       | 150 mmHg                                  |
| Systolic Blood Pressure units       | MMHG                                      |
| Diastolic Blood Pressure (xxx)      | 98 mmHg                                   |
| Diastolic Blood Pressure units      | MMHG                                      |

US3222220

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 22:18:04

Generated On: 09 Jun 2021 16:05:20

|                                     |   |
|-------------------------------------|---|
| 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)    | 17 SEP 2020                                   |
| Time of assessment (00:00-23:59)    | 10:15 (24 HR)                                 |
| Vital Signs Date and Time (derived) | 17 SEP 2020 10:15                             |
| Temperature (xxx.x)                 | 37.0 C  |
| Route of measurement                | Oral <input checked="" type="checkbox"/>      |
|                                     | Axillary <input type="checkbox"/>             |
|                                     | Other <input type="checkbox"/>                |
| If Other, specify                   |   |
| Pulse (xxx)                         | 70 beats/min                                  |
| Pulse units                         | BPM   |
| Respiratory Rate (xxx)              | 18 breaths/min                                |
| Respiratory Rate units              | BREATHS/MIN                                   |
| Systolic Blood Pressure (xxx)       | 150 mmHg                                      |
| Systolic Blood Pressure units       | MMHG  |
| Diastolic Blood Pressure (xxx)      | 90 mmHg                                       |
| Diastolic Blood Pressure units      | MMHG  |

US3222220

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 22:18:04

Generated On: 09 Jun 2021 16:05:20

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

17 SEP 2020

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

US3222220

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 22:18:04

Generated On: 09 Jun 2021 16:05:20

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) 17 SEP 2020

What was the treatment time? (00:00-23:59) 09:32 (24 HR)

Treatment Date and Time (derived) 17 SEP 2020 09:32

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

US3222220

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 22:18:04

Generated On: 09 Jun 2021 16:05:20

|                                    |                                      |
|------------------------------------|--------------------------------------|
| Was the sample collected?          | Yes <input checked="" type="radio"/> |
|                                    | No <input type="radio"/>             |
| Collection date (dd MMM yyyy)      | 17 SEP 2020                          |
| Collection time (00:00-23:59)      | 08:55 (24 HR)                        |
| Collection date and time (derived) | 17 SEP 2020 08:55                    |

US3222220

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 22:18:04

Generated On: 09 Jun 2021 16:05:20

|                               |                           |                                 |                                    |
|-------------------------------|---------------------------|---------------------------------|------------------------------------|
| Collection date (dd MMM yyyy) |                           |                                 | 17 SEP 2020                        |
| Lab Test                      | Was the sample collected? | Collection time (00:00 - 23:59) | Collection date and time (derived) |
| Nasopharyngeal Swab 1         | Yes                       | 08:57                           | 17 SEP 2020 08:57                  |
| Nasopharyngeal Swab 2         | No                        |                                 |                                    |

US3222220

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 22:18:04

Generated On: 09 Jun 2021 16:05:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:05:20

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °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

17 SEP 2020 10:15

PC Open Date & Time

17 SEP 2020 09:52

PC Close Date & Time

17 SEP 2020 12:22



US3222220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:05:20

**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 98.5 °F

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

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

|                      |                   |
|----------------------|-------------------|
| PC Time Stamp        | 17 SEP 2020 20:38 |
| PC Open Date & Time  | 17 SEP 2020 13:17 |
| PC Close Date & Time | 18 SEP 2020 11:59 |

US3222220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:05:20

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 SEP 2020 19:28

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3222220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:05:20

**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

98.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 SEP 2020 12:01

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3222220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:05:20

**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

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 SEP 2020 12:02

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3222220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:05:20

**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

99.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 SEP 2020 12:05

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3222220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:05:20

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**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 SEP 2020 12:03

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3222220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:05:20

**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

98.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 SEP 2020 15:09

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3222220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:05:20

**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

17 SEP 2020 10:15

PC Open Date & Time

17 SEP 2020 09:52

PC Close Date & Time

17 SEP 2020 12:22



US3222220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:05:20

**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

17 SEP 2020 20:38

PC Open Date & Time

17 SEP 2020 13:17

PC Close Date & Time

18 SEP 2020 11:59

US3222220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:05:20

**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

18 SEP 2020 19:29

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3222220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:05:20

**TIMEPOINT**

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

19 SEP 2020 12:02

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3222220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:05:20

**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

20 SEP 2020 12:03

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3222220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:05:20

**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

21 SEP 2020 12:05

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3222220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:05:20

**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

22 SEP 2020 12:03

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3222220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:05:20

**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

23 SEP 2020 15:10

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3222220

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:05:20

**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 ☐



US3222220

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:05:20

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

No ☒

Yes ☐

|                      |                   |
|----------------------|-------------------|
| PC Time stamp        | 17 SEP 2020 10:16 |
| PC Open Date & Time  | 17 SEP 2020 09:52 |
| PC Close Date & Time | 17 SEP 2020 12:22 |

US3222220

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:05:20

**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 ☐

US3222220

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:05:20

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

No ☒

Yes ☐

|                      |                   |
|----------------------|-------------------|
| PC Time stamp        | 17 SEP 2020 20:39 |
| PC Open Date & Time  | 17 SEP 2020 13:17 |
| PC Close Date & Time | 18 SEP 2020 11:59 |

US3222220

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:05:20

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 ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3222220

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:05:20

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 18 SEP 2020 19:30 |
| PC Open Date & Time          | 18 SEP 2020 12:00 |
| PC Close Date & Time         | 19 SEP 2020 11:59 |

US3222220

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:05:20

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

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EAB) (1725)

US3222220

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:05:20

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

US3222220

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:05:20

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 ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3222220

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:05:20

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 20 SEP 2020 12:03 |
| PC Open Date & Time          | 20 SEP 2020 12:00 |
| PC Close Date & Time         | 21 SEP 2020 11:59 |

US3222220

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:05:20

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 ☒

US3222220

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:05:20

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 21 SEP 2020 12:06 |
| PC Open Date & Time          | 21 SEP 2020 12:00 |
| PC Close Date & Time         | 22 SEP 2020 11:59 |

US3222220

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:05:20

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 ☒

US3222220

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:05:20

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 22 SEP 2020 12:04 |
| PC Open Date & Time          | 22 SEP 2020 12:00 |
| PC Close Date & Time         | 23 SEP 2020 11:59 |

US3222220

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:05:20

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 ☒

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Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:05:20

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 23 SEP 2020 15:10 |
| PC Open Date & Time          | 23 SEP 2020 12:00 |
| PC Close Date & Time         | 24 SEP 2020 11:59 |

US3222220

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 22:18:04

Generated On: 09 Jun 2021 16:05:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3222220

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 22:18:04

Generated On: 09 Jun 2021 16:05:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222220

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 22:18:04

Generated On: 09 Jun 2021 16:05:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3222220

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 22:18:04

Generated On: 09 Jun 2021 16:05:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222220

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 22:18:04

Generated On: 09 Jun 2021 16:05:20

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 8 OCT 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3222220

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 22:18:04

Generated On: 09 Jun 2021 16:05:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222220

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 22:18:04

Generated On: 09 Jun 2021 16:05:20

|   |   |
|---|---|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|   | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)  | 20 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                                  |

US3222220

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 22:18:05

Generated On: 09 Jun 2021 16:05:20

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) \_\_\_\_\_

US3222220

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 22:18:04

Generated On: 09 Jun 2021 16:05:20

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.*



US3222220

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 22:18:04

Generated On: 09 Jun 2021 16:05:20

|                                    |                                      |
|------------------------------------|--------------------------------------|
| Was the sample collected?          | Yes <input checked="" type="radio"/> |
|                                    | No <input type="radio"/>             |
| Collection date (dd MMM yyyy)      | 20 OCT 2020                          |
| Collection time (00:00-23:59)      | 13:55 (24 HR)                        |
| Collection date and time (derived) | 20 OCT 2020 13:55                    |

US3222220

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 22:18:04

Generated On: 09 Jun 2021 16:05:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222220

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

| TIMEPOINT   | DAY 64  |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>   |
| 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="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |

US3222220

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

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

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

Date and time of submission

Patient Cloud Open Date & Time

19 OCT 2020 00:01

Patient Cloud Close Date & Time

23 OCT 2020 23:59

US3222220

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

**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

26 OCT 2020 21:43:07

Patient Cloud Open Date & Time

26 OCT 2020 00:01

Patient Cloud Close Date & Time

30 OCT 2020 23:59

US3222220

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

| TIMEPOINT   | DAY 78  |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |   |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>  |
| Chills  | <input type="checkbox"/>  |
| Cough   | <input type="checkbox"/>  |
| Shortness of breath   | <input type="checkbox"/>  |
| Difficulty breathing  | <input type="checkbox"/>  |
| Fatigue   | <input type="checkbox"/>  |
| Muscle aches  | <input type="checkbox"/>  |
| Body aches  | <input type="checkbox"/>  |
| Headache  | <input type="checkbox"/>  |
| New loss of taste   | <input type="checkbox"/>  |
| New loss of smell   | <input type="checkbox"/>  |
| Sore throat   | <input type="checkbox"/>  |
| Congestion  | <input type="checkbox"/>  |
| Runny nose  | <input type="checkbox"/>  |
| Nausea  | <input type="checkbox"/>  |
| Vomiting  | <input type="checkbox"/>  |
| Diarrhea  | <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |

US3222220

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

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

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

Date and time of submission

Patient Cloud Open Date & Time

02 NOV 2020 00:01

Patient Cloud Close Date & Time

06 NOV 2020 23:59

US3222220

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

| TIMEPOINT   | DAY 92  |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |   |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>  |
| Chills  | <input type="checkbox"/>  |
| Cough   | <input type="checkbox"/>  |
| Shortness of breath   | <input type="checkbox"/>  |
| Difficulty breathing  | <input type="checkbox"/>  |
| Fatigue   | <input type="checkbox"/>  |
| Muscle aches  | <input type="checkbox"/>  |
| Body aches  | <input type="checkbox"/>  |
| Headache  | <input type="checkbox"/>  |
| New loss of taste   | <input type="checkbox"/>  |
| New loss of smell   | <input type="checkbox"/>  |
| Sore throat   | <input type="checkbox"/>  |
| Congestion  | <input type="checkbox"/>  |
| Runny nose  | <input type="checkbox"/>  |
| Nausea  | <input type="checkbox"/>  |
| Vomiting  | <input type="checkbox"/>  |
| Diarrhea  | <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |



US3222220

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

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

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 NOV 2020 00:01

Patient Cloud Close Date & Time

20 NOV 2020 23:59

US3222220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

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

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

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

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[Patient Cloud Close Date & Time](#)

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24 NOV 2020 23:59

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US3222220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

**TIMEPOINT**

DAY 103

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

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

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

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

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

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

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

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

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

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

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[Patient Cloud Close Date & Time](#)

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01 DEC 2020 23:59

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US3222220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

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

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

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

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[Patient Cloud Close Date & Time](#)

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08 DEC 2020 23:59

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US3222220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

**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 contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐



**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

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

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[Patient Cloud Close Date & Time](#)

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15 DEC 2020 23:59

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US3222220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

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

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

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

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[Patient Cloud Close Date & Time](#)

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22 DEC 2020 23:59

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US3222220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

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

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

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

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Date and time of submission

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|  |                   |
|--|-------------------|
| <a href="#">Patient Cloud Open Date &amp; Time</a> | 25 DEC 2020 00:01 |
|--|-------------------|

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|   |                   |
|---|-------------------|
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 29 DEC 2020 23:59 |
|---|-------------------|

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US3222220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

**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 contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

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

US3222220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

**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 contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐



**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

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

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[Patient Cloud Close Date & Time](#)

12 JAN 2021 23:59

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US3222220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

**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 contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

19 JAN 2021 23:59

US3222220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

**TIMEPOINT**

DAY 159

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

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

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

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

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

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

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

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

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

26 JAN 2021 23:59

US3222220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

| TIMEPOINT   | DAY 166  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="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"/>  |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

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

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[Patient Cloud Close Date & Time](#)

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02 FEB 2021 23:59

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US3222220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

**TIMEPOINT**

DAY 173

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐



**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

05 FEB 2021 00:01

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[Patient Cloud Close Date & Time](#)

09 FEB 2021 23:59

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US3222220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

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

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

12 FEB 2021 00:01

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[Patient Cloud Close Date & Time](#)

16 FEB 2021 23:59

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US3222220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

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

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

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

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[Patient Cloud Close Date & Time](#)

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23 FEB 2021 23:59

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US3222220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

| TIMEPOINT   | DAY 194  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="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"/>  |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 FEB 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 02 MAR 2021 23:59 |

US3222220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

| TIMEPOINT   | DAY 201  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="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"/>  |



**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

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

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[Patient Cloud Close Date & Time](#)

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09 MAR 2021 23:59

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US3222220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

**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 contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

12 MAR 2021 00:01

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[Patient Cloud Close Date & Time](#)

16 MAR 2021 23:59

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US3222220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

**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 contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

23 MAR 2021 23:59

US3222220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

**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 contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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26 MAR 2021 00:01

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[Patient Cloud Close Date & Time](#)

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30 MAR 2021 23:59

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US3222220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

**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 contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐



**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

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

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[Patient Cloud Close Date & Time](#)

06 APR 2021 23:59

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US3222220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

| TIMEPOINT   | DAY 236  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="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"/>  |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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09 APR 2021 00:01

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[Patient Cloud Close Date & Time](#)

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13 APR 2021 23:59

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US3222220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

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

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 APR 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 20 APR 2021 23:59 |

US3222220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

**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 ☐  
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 ☐

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

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

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[Patient Cloud Close Date & Time](#)

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27 APR 2021 23:59

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US3222220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

**TIMEPOINT**

DAY 257

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

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

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

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

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

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

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

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



**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

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

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[Patient Cloud Close Date & Time](#)

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04 MAY 2021 23:59

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US3222220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

**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 ☐  
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 ☐

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3222220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

**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 ☐

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3222220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

**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°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 ☐

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

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

21 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

25 MAY 2021 23:59

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US3222220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

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



**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3222220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

**TIMEPOINT**

DAY 292

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3222220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

| 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"/>   |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

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

US3222220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

**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 ☐

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

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

US3222220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

**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 ☐



**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

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

US3222220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

**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 ☐  
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 ☐

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

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

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[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

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US3222220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

**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 ☐

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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09 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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13 JUL 2021 23:59

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US3222220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

**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 ☐  
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 ☐

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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16 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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20 JUL 2021 23:59

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US3222220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

| 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="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"/>  |



**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

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

US3222220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

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

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3222220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

**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 ☐

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3222220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

**TIMEPOINT**

DAY 362

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

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

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Date and time of submission

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|  |                   |
|--|-------------------|
| <a href="#">Patient Cloud Open Date &amp; Time</a> | 13 AUG 2021 00:01 |
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|   |                   |
|---|-------------------|
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 17 AUG 2021 23:59 |
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US3222220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

**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 ☐



**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3222220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

**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 ☐

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

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

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[Patient Cloud Close Date & Time](#)

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31 AUG 2021 23:59

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US3222220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

**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 ☐

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3222220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

**TIMEPOINT**

DAY 390

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

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

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

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

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

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

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

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

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2021 23:59

US3222220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

**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 ☐



**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3222220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

| 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"/>  |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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24 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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28 SEP 2021 23:59

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US3222220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

| 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°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="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

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

US3222220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

**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 ☐

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

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

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[Patient Cloud Close Date & Time](#)

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12 OCT 2021 23:59

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US3222220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

**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 ☐



**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

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

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Date and time of submission

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|  |                   |
|--|-------------------|
| <a href="#">Patient Cloud Open Date &amp; Time</a> | 15 OCT 2021 00:01 |
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|   |                   |
|---|-------------------|
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 19 OCT 2021 23:59 |
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US3222220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

**TIMEPOINT**

DAY 432

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

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

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

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

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

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

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

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

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

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

US3222220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

**TIMEPOINT**

DAY 439

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3222220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

| 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"/>  |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

05 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

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US3222220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

**TIMEPOINT**

DAY 453

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

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

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

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

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

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

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

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



**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

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

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Date and time of submission

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|  |                   |
|--|-------------------|
| <a href="#">Patient Cloud Open Date &amp; Time</a> | 12 NOV 2021 00:01 |
|--|-------------------|

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|   |                   |
|---|-------------------|
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 16 NOV 2021 23:59 |
|---|-------------------|

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US3222220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

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

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3222220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

**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 ☐

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

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

US3222220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

**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 ☐

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 07 DEC 2021 23:59 |

US3222220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

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



**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

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

US3222220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

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

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3222220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

**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 ☐  
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 ☐

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

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

US3222220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

**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°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 ☐

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3222220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

**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 ☐



**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

07 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

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US3222220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

| 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"/>   |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3222220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

**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 ☐

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

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

US3222220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

**TIMEPOINT**

DAY 530

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

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

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

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

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

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

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

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

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3222220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

**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 ☐



**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3222220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

**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 ☐

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

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

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[Patient Cloud Close Date & Time](#)

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15 FEB 2022 23:59

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US3222220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

**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°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 ☐

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3222220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

**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 ☐

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3222220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

**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 ☐



**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3222220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

**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°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 ☐

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

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

US3222220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

**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°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 ☐

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

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

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[Patient Cloud Close Date & Time](#)

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22 MAR 2022 23:59

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US3222220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

**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 ☐

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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|  |                   |
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| <a href="#">Patient Cloud Open Date &amp; Time</a> | 25 MAR 2022 00:01 |
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|   |                   |
|---|-------------------|
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 29 MAR 2022 23:59 |
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US3222220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

**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 ☐



**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

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

01 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

05 APR 2022 23:59

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US3222220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

| 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°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"/>  |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

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

US3222220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

| 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"/>  |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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15 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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19 APR 2022 23:59

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US3222220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

| 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"/>  |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

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

US3222220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

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



**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3222220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

**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 ☐

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3222220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

**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 ☐

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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13 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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17 MAY 2022 23:59

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US3222220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

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

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

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

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[Patient Cloud Close Date & Time](#)

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24 MAY 2022 23:59

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US3222220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

| 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="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"/>  |



**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3222220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

**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 ☐

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

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

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[Patient Cloud Close Date & Time](#)

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07 JUN 2022 23:59

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US3222220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

**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 ☐

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3222220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

**TIMEPOINT**

DAY 670

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

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

US3222220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

**TIMEPOINT**

DAY 677

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

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

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

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

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

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

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

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



**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2022 23:59

US3222220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

| 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"/>  |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

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

US3222220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

| TIMEPOINT   | DAY 691   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |   |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>  |
| Chills  | <input type="checkbox"/>  |
| Cough   | <input type="checkbox"/>  |
| Shortness of breath   | <input type="checkbox"/>  |
| Difficulty breathing  | <input type="checkbox"/>  |
| Fatigue   | <input type="checkbox"/>  |
| Muscle aches  | <input type="checkbox"/>  |
| Body aches  | <input type="checkbox"/>  |
| Headache  | <input type="checkbox"/>  |
| New loss of taste   | <input type="checkbox"/>  |
| New loss of smell   | <input type="checkbox"/>  |
| Sore throat   | <input type="checkbox"/>  |
| Congestion  | <input type="checkbox"/>  |
| Runny nose  | <input type="checkbox"/>  |
| Nausea  | <input type="checkbox"/>  |
| Vomiting  | <input type="checkbox"/>  |
| Diarrhea  | <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

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

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[Patient Cloud Close Date & Time](#)

12 JUL 2022 23:59

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US3222220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

**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 ☐

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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15 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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19 JUL 2022 23:59

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US3222220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

**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 ☐



**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

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

US3222220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

| 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"/>   |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>  | 29 JUL 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 02 AUG 2022 23:59 |

US3222220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

**TIMEPOINT**

DAY 719

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

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

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

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

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

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

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

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

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3222220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

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

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3222220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

**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 ☐  
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 ☐



**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

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

US3222220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

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

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

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

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

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US3222220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

**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 ☐ 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 ☐

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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02 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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06 SEP 2022 23:59

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US3222220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

**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 ☐  
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 ☐

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

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

US3222220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

**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°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 ☐



**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

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

[Patient Cloud Open Date & Time](#)

16 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2022 23:59

US3222220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

**TIMEPOINT**

DAY 768

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

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

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

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

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

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

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

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

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

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

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[Patient Cloud Close Date & Time](#)

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27 SEP 2022 23:59

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US3222220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

**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 ☐

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

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

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[Patient Cloud Close Date & Time](#)

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04 OCT 2022 23:59

US3222220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

**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 ☐

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

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

US3222220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

**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 ☐



**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

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

US3222220

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

| TIMEPOINT   | DAY 796   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |   |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>  |
| Chills  | <input type="checkbox"/>  |
| Cough   | <input type="checkbox"/>  |
| Shortness of breath   | <input type="checkbox"/>  |
| Difficulty breathing  | <input type="checkbox"/>  |
| Fatigue   | <input type="checkbox"/>  |
| Muscle aches  | <input type="checkbox"/>  |
| Body aches  | <input type="checkbox"/>  |
| Headache  | <input type="checkbox"/>  |
| New loss of taste   | <input type="checkbox"/>  |
| New loss of smell   | <input type="checkbox"/>  |
| Sore throat   | <input type="checkbox"/>  |
| Congestion  | <input type="checkbox"/>  |
| Runny nose  | <input type="checkbox"/>  |
| Nausea  | <input type="checkbox"/>  |
| Vomiting  | <input type="checkbox"/>  |
| Diarrhea  | <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

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

US3222220

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 09 Jun 2021 16:05:20

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

US3222220

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 22:18:04

Generated On: 09 Jun 2021 16:05:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3222220

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 22:18:04

Generated On: 09 Jun 2021 16:05:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222220

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 22:18:04

Generated On: 09 Jun 2021 16:05:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3222220

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 22:18:04

Generated On: 09 Jun 2021 16:05:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3222220

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 22:18:04

Generated On: 09 Jun 2021 16:05:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3222220

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 22:18:04

Generated On: 09 Jun 2021 16:05:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222220

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 22:18:04

Generated On: 09 Jun 2021 16:05:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3222220

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 22:18:04

Generated On: 09 Jun 2021 16:05:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222220

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 13:56:59

Generated On: 09 Jun 2021 16:05:20

|   |   |
|---|---|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|   | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)  | 7 APR 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                                  |

US3222220

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Apr 2021 13:56:59

Generated On: 09 Jun 2021 16:05:20

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) \_\_\_\_\_

US3222220

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 13:56:59

Generated On: 09 Jun 2021 16:05:20

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.*

US3222220

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Apr 2021 13:56:59

Generated On: 09 Jun 2021 16:05:20

|                                    |                                      |
|------------------------------------|--------------------------------------|
| Was the sample collected?          | Yes <input checked="" type="radio"/> |
|                                    | No <input type="radio"/>             |
| Collection date (dd MMM yyyy)      | 7 APR 2021                           |
| Collection time (00:00-23:59)      | 10:20 (24 HR)                        |
| Collection date and time (derived) | 7 APR 2021 10:20                     |



US3222220

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 13:56:59

Generated On: 09 Jun 2021 16:05:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222220

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 13:56:58

Generated On: 09 Jun 2021 16:05:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3222220

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 13:56:58

Generated On: 09 Jun 2021 16:05:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222220

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:20

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*

**US3222220**

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

**Form: Continuing**

**Generated On: 09 Jun 2021 16:05:20**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3222220

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:05:20

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

**US3222220**

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

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

**Generated On: 09 Jun 2021 16:05:20**

---

Generate Next COVID-19 Assessment

Yes ☐

No ☐

---

US3222220

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

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 13:56:58

Generated On: 09 Jun 2021 16:05:20

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

|                          |            |
|--------------------------|------------|
| Visit date (dd MMM yyyy) | 7 APR 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 |
|------------|---------------|



US3222220

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

Form: Unblinding

Data signed: (b) (4) 26 Apr 2021 13:56:58

Generated On: 09 Jun 2021 16:05:20

|   |   |
|---|---|
| Date of updated informed consent ( <i>dd MMM yyyy</i> )               | 7 APR 2021  |
| N/A - Subject Unblinded under Amendment 5 and Discontinued from Study | False   |
| Was the participant unblinded?  | Yes <input checked="" type="radio"/><br>No <input type="radio"/>  |
| Under what version of the Protocol was the Participant unblinded?     | Amendment 5 <input type="radio"/><br>Amendment 6 or later <input checked="" type="radio"/>                            |
| Date of unblinding ( <i>dd MMM yyyy</i> )                             | 7 APR 2021  |
| Participant randomization assignment                                  | mRNA-1273 <input type="radio"/><br>Placebo <input checked="" type="radio"/>   |
| Actual Dose 1   | mRNA-1273 <input type="radio"/><br>Placebo <input checked="" type="radio"/><br>Not Administered <input type="radio"/> |
| Actual Dose 2   | mRNA-1273 <input type="radio"/><br>Placebo <input checked="" type="radio"/><br>Not Administered <input type="radio"/> |
| Will participant receive mRNA-1273?                                   | Yes <input type="radio"/><br>No <input checked="" type="radio"/>  |
| Placebo Only Flag   | 1   |
| Continuing with mRNA-1273   |   |

US3222220

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Apr 2021 13:56:58

Generated On: 09 Jun 2021 16:05:20

|                                    |                                      |
|------------------------------------|--------------------------------------|
| Was the sample collected?          | Yes <input checked="" type="radio"/> |
|                                    | No <input type="radio"/>             |
| Collection date (dd MMM yyyy)      | 7 APR 2021                           |
| Collection time (00:00-23:59)      | 10:20 (24 HR)                        |
| Collection date and time (derived) | 7 APR 2021 10:20                     |

US3222220

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 26 Apr 2021 13:56:58

Generated On: 09 Jun 2021 16:05:20

|                                    |                                      |
|------------------------------------|--------------------------------------|
| Was the sample collected?          | Yes <input checked="" type="radio"/> |
|                                    | No <input type="radio"/>             |
| Collection date (dd MMM yyyy)      | 7 APR 2021                           |
| Collection time (00:00 - 23:59)    | 10:23                                |
| Collection Date and Time (derived) | 7 APR 2021 10:23                     |

US3222220

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 28 Apr 2021 22:12:59

Generated On: 09 Jun 2021 16:05:20

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3222220

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:20

|  |  |
|--|--|
| AEID   | USA-US104-2021-MRNA-1273-P30<br>1000015  |
| Adverse event  | TEMPORAL ARTERY BLEEDING   |
| 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)                                       | 11 MAR 2021  |
| Start time (00:00-23:59)                                       |  |
| AE start date and time (derived)                               |  |
| Ongoing?   | Yes <input type="radio"/><br>No <input checked="" type="radio"/>   |
| If not Ongoing, end date (dd MMM yyyy)                         | 15 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 type="radio"/><br>Grade 4 <input checked="" type="radio"/> |
| Is the adverse event serious?                                  | Yes <input checked="" type="radio"/><br>No <input type="radio"/>   |
| AE is serious due To (check all that apply)                    |  |
| Death  | False  |
| Life threatening   | False  |
| Requires inpatient or prolongation of existing Hospitalization | True   |
| Hospital Admission Date (dd MMM yyyy)                          | 11 MAR 2021  |
| Hospital Discharge Date (dd MMM yyyy)                          | 15 MAR 2021  |
| Admitted to ICU?   | Yes <input type="radio"/><br>No <input checked="" type="radio"/><br>Unknown <input type="radio"/>  |
| Number of Days in ICU  |  |

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3222220

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:20

|  |   |
|--|---|
| Persistent or significant disability or incapacity                           | False   |
| Congenital anomaly or birth defect   | False   |
| Other medically important event  | False   |
| Relationship to investigational product                                      | Not Related <input checked="" type="radio"/><br>Related <input type="radio"/><br>Not Applicable <input type="radio"/>   |
| Relationship to Study Procedure  | Not Related <input checked="" type="radio"/><br>Related <input type="radio"/><br>Not Applicable <input type="radio"/>   |
| Action taken with investigational product                                    | None <input type="radio"/><br>Dose Delayed <input type="radio"/><br>Investigational Product <input type="radio"/><br>Withdrawn <input type="radio"/><br>Not Applicable <input checked="" type="radio"/>   |
| Other action taken (check all that apply)                                    |   |
| None   | False   |
| Concomitant Medication   | True  |
| Concomitant Procedure  | False   |
| Outcome  | Fatal <input type="radio"/><br>Not Recovered/Not Resolved <input type="radio"/><br>Recovered/Resolved <input checked="" type="radio"/><br>Recovered/Resolved with Sequelae <input type="radio"/><br>Recovering/Resolving <input type="radio"/><br>Unknown <input type="radio"/> |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: |   |
| Narrative  | SAE HOSPITALIZED 12 MAR 2021  |
| 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   |

US3222220

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:20

|  |  |
|--|--|
| AEID   | USA-US104-2021-MRNA-1273-P30   |
|  | 1000015  |
| Adverse event  | FALL   |
| 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)                                       | 12 MAR 2021  |
| Start time (00:00-23:59)                                       |  |
| AE start date and time (derived)                               |  |
| Ongoing?   | Yes <input checked="" type="radio"/><br>No <input type="radio"/>   |
| If not Ongoing, end date (dd MMM yyyy)                         |  |
| End time (00:00-23:59)   |  |
| AE End Date and Time (derived)                                 |  |
| Severity   | Grade 1/Mild <input type="radio"/><br>Grade 2/Moderate <input type="radio"/><br>Grade 3/Severe <input type="radio"/><br>Grade 4 <input checked="" type="radio"/> |
| Is the adverse event serious?                                  | Yes <input checked="" type="radio"/><br>No <input type="radio"/>   |
| AE is serious due To (check all that apply)                    |  |
| Death  | False  |
| Life threatening   | False  |
| Requires inpatient or prolongation of existing Hospitalization | True   |
| Hospital Admission Date (dd MMM yyyy)                          |  |
| Hospital Discharge Date (dd MMM yyyy)                          |  |
| Admitted to ICU?   | Yes <input type="radio"/><br>No <input type="radio"/><br>Unknown <input type="radio"/>   |
| Number of Days in ICU  |  |

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3222220

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:20

|  |   |
|--|---|
| Persistent or significant disability or incapacity                           | False   |
| Congenital anomaly or birth defect   | False   |
| Other medically important event  | False   |
| Relationship to investigational product                                      | Not Related <input checked="" type="radio"/><br>Related <input type="radio"/><br>Not Applicable <input type="radio"/>   |
| Relationship to Study Procedure  | Not Related <input checked="" type="radio"/><br>Related <input type="radio"/><br>Not Applicable <input type="radio"/>   |
| Action taken with investigational product                                    | None <input type="radio"/><br>Dose Delayed <input type="radio"/><br>Investigational Product <input type="radio"/><br>Withdrawn <input type="radio"/><br>Not Applicable <input checked="" type="radio"/>   |
| Other action taken (check all that apply)                                    |   |
| None   | False   |
| Concomitant Medication   | True  |
| Concomitant Procedure  | False   |
| Outcome  | Fatal <input type="radio"/><br>Not Recovered/Not Resolved <input type="radio"/><br>Recovered/Resolved <input type="radio"/><br>Recovered/Resolved with Sequelae <input type="radio"/><br>Recovering/Resolving <input type="radio"/><br>Unknown <input checked="" type="radio"/> |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: |   |
| Narrative  | SAE HOSPITALIZED<br>12/MAR/2021   |
| 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)                         |   |



US3222220

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 19 Feb 2021 22:18:04

Generated On: 09 Jun 2021 16:05:20

---

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

Yes ☒

No ☐

---

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

---

US3222220

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 19 Feb 2021 22:18:04

Generated On: 09 Jun 2021 16:05:20

Name of Medication PROTONIX

Prophylaxis Yes ☐  
No ☒

Indication GERD

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3222220

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 19 Feb 2021 22:18:04

Generated On: 09 Jun 2021 16:05:20

|  |                          |                                  |
|--|--------------------------|----------------------------------|
|  | Intramuscular            | <input type="checkbox"/>         |
|  | Respiratory (Inhalation) | <input type="checkbox"/>         |
|  | Intralesional            | <input type="checkbox"/>         |
|  | Intraperitoneal          | <input type="checkbox"/>         |
|  | Nasal                    | <input type="checkbox"/>         |
|  | Vaginal                  | <input type="checkbox"/>         |
|  | Rectal                   | <input type="checkbox"/>         |
|  | Intravenous              | <input type="checkbox"/>         |
|  | Intravenous Bolus        | <input type="checkbox"/>         |
|  | Intravenous Drip         | <input type="checkbox"/>         |
|  | Other                    | <input type="checkbox"/>         |
| If route of administration is Other, specify _____ |                          |                                  |
| Start date (dd MMM yyyy)                           | UN UNK 2019              |                                  |
| 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"/>            |

US3222220

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 19 Feb 2021 22:18:04

Generated On: 09 Jun 2021 16:05:20

---

Were any concomitant procedures performed?

Yes ☐

No ☒

---

If yes, please complete Concomitant Procedures form.

---

US3222220

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 16:05:20

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by  
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent  
by participant, Protocol deviation, or Other, specify

US3222220

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:05:20

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 ☐

US3222220

Folder: SAE USA-US104-2021-MRNA-1273-P301000015

Form: Safety Report Form

Data signed: (b) (4) 28 Apr 2021 22:12:59

Generated On: 09 Jun 2021 16:05:20

|  |  |
|--|--|
| SAEID  | USA-US104-2021-MRNA-1273-P301000015                              |
| 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                                      | BRUCE  |
| Investigator's Last Name                                       | RANKIN   |
| Site Address: Street   | 860 PEACHWOOD AVE  |
| Site Address: City   | DELAND   |
| Site Address: State  |  |
| Site Address: Postal Code                                      | 32720  |
| Investigator Country   | US   |
| E2B Transmit Flag (Derived/Hidden)                             | 5  |

US3222220

Folder: SAE USA-US104-2021-MRNA-1273-P301000015

Form: Safety Report Form (1)

Data signed: (b) (4) 28 Apr 2021 22:12:59

Generated On: 09 Jun 2021 16:05:20

|   |  |
|---|--|
| SAEID   | USA-US104-2021-MRNA-1273-P301000015                              |
| 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   | BRUCE  |
| Investigator's Last Name  | RANKIN   |
| Site Address: Street  | 860 PEACHWOOD AVE  |
| Site Address: City  | DELAND   |
| Site Address: State   |  |
| Site Address: Postal Code   | 32720  |
| Investigator Country  | US   |
| E2B Transmit Flag (Derived/Hidden)  | 5  |
| Date of submission (Pre-filled from custom function)  | 17/MAR/2021 10:14  |
| 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   |



US3222220

Folder: SAE USA-US104-2021-MRNA-1273-P301000015

Form: Safety Report Form (2)

Data signed: (b) (4) 28 Apr 2021 22:12:59

Generated On: 09 Jun 2021 16:05:20

|   |  |
|---|--|
| SAEID   | USA-US104-2021-MRNA-1273-P301000015                              |
| 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   | BRUCE  |
| Investigator's Last Name  | RANKIN   |
| Site Address: Street  | 860 PEACHWOOD AVE  |
| Site Address: City  | DELAND   |
| Site Address: State   |  |
| Site Address: Postal Code   | 32720  |
| Investigator Country  | US   |
| E2B Transmit Flag (Derived/Hidden)  | 5  |
| Date of submission (Pre-filled from custom function)  | 07/APR/2021 11:09  |
| 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   |

US3222220

Folder: SAE USA-US104-2021-MRNA-1273-P301000015

Form: Safety Report Form (3)

Data signed: (b) (4) 28 Apr 2021 22:12:59

Generated On: 09 Jun 2021 16:05:20

|   |  |
|---|--|
| SAEID   | USA-US104-2021-MRNA-1273-P301000015                              |
| 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   | BRUCE  |
| Investigator's Last Name  | RANKIN   |
| Site Address: Street  | 860 PEACHWOOD AVE  |
| Site Address: City  | DELAND   |
| Site Address: State   |  |
| Site Address: Postal Code   | 32720  |
| Investigator Country  | US   |
| E2B Transmit Flag (Derived/Hidden)  | 5  |
| Date of submission (Pre-filled from custom function)  | 14/APR/2021 06:21  |
| 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   |

US3222220

Folder: SAE USA-US104-2021-MRNA-1273-P301000015

Form: Safety Report Form (4)

Data signed: (b) (4) 28 Apr 2021 22:12:59

Generated On: 09 Jun 2021 16:05:20

|   |  |
|---|--|
| SAEID   | USA-US104-2021-MRNA-1273-P301000015                              |
| 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   | BRUCE  |
| Investigator's Last Name  | RANKIN   |
| Site Address: Street  | 860 PEACHWOOD AVE  |
| Site Address: City  | DELAND   |
| Site Address: State   |  |
| Site Address: Postal Code   | 32720  |
| Investigator Country  | US   |
| E2B Transmit Flag (Derived/Hidden)  | 5  |
| Date of submission (Pre-filled from custom function)  | 15/APR/2021 09:32  |
| Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge. | True   |

US3222220

Folder: SAE USA-US104-2021-MRNA-1273-P301000015

Form: Safety Report Form (5)

Data signed: (b) (4) 28 Apr 2021 22:12:59

Generated On: 09 Jun 2021 16:05:20

|   |  |
|---|--|
| SAEID   | USA-US104-2021-MRNA-1273-P301000015                              |
| 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   | BRUCE  |
| Investigator's Last Name  | RANKIN   |
| Site Address: Street  | 860 PEACHWOOD AVE  |
| Site Address: City  | DELAND   |
| Site Address: State   |  |
| Site Address: Postal Code   | 32720  |
| Investigator Country  | US   |
| E2B Transmit Flag (Derived/Hidden)  | 5  |
| Date of submission (Pre-filled from custom function)  | 26/APR/2021 13:52  |
| 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

US3222220 (Prod: Accel Research Site - Avail - ERN-PPDS)

**US3222220**

**Form: Participant Creation**

**Generated On: 09 Jun 2021 16:05:20**

[Participant ID](#)

| Audit                     | User  | Time (GMT)           |
|---------------------------|---|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4)                        | 19 Feb 2021 22:18:05 |
| User entered 'US3222220'  | (b) (4)<br>RWS_ENDPOINT<br>ENDPOINT (b) (4) | 19 Aug 2020 15:04:32 |

US3222220

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:05:20

[Was this visit performed?](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 27 Apr 2021 13:56:47 |
| User signature succeeded. | Bruce Rankin (b) (4)     | 19 Feb 2021 22:18:05 |
| User entered 'Yes (Y)'    | Jennifer Dittman (b) (4) | 19 Aug 2020 15:09:03 |

US3222220

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:05:20

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

| Audit                      | User  | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                            | 27 Apr 2021 13:56:47 |
| User signature succeeded.  | Bruce Rankin (b) (4)                        | 19 Feb 2021 22:18:05 |
| User entered '19 AUG 2020' | (b) (4)<br>RWS_ENDPOINT<br>ENDPOINT (b) (4) | 19 Aug 2020 15:04:33 |



US3222220

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:05:20

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

| Audit                          | User                     | Time (GMT)           |
|--------------------------------|--------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)         | 27 Apr 2021 13:56:47 |
| User signature succeeded.      | Bruce Rankin (b) (4)     | 19 Feb 2021 22:18:05 |
| User entered 'Clinic (Clinic)' | Jennifer Dittman (b) (4) | 19 Aug 2020 15:09:03 |

US3222220

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:05:20

[Folder OID](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 13:56:47 |
| User entered 'SCRN' | System           | 19 Aug 2020 15:09:03 |

US3222220

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:05:20

Date of Birth (MMM yyyy)

| Audit                      | User  | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                            | 27 Apr 2021 13:56:47 |
| User signature succeeded.  | Bruce Rankin (b) (4)                        | 19 Feb 2021 22:18:05 |
| User entered (b) (6) 1956' | (b) (4)<br>RWS_ENDPOINT<br>ENDPOINT (b) (4) | 19 Aug 2020 15:04:34 |

US3222220

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:05:20

[Age](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 27 Apr 2021 13:56:47 |
| User signature succeeded. | Bruce Rankin (b) (4)  | 19 Feb 2021 22:18:05 |
| User entered '63'         | Amber Vasquez (b) (4) | 19 Aug 2020 19:15:18 |

US3222220

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:05:20

[Age Units](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 27 Apr 2021 13:56:47 |
| User entered 'YEARS' | System           | 19 Aug 2020 19:15:18 |

US3222220

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:05:20

[Age \(Derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 13:56:47 |
| User entered '63' | System           | 19 Aug 2020 15:09:34 |

US3222220

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:05:20

Sex

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 13:56:47 |
| User signature succeeded. | Bruce Rankin (b) (4)             | 19 Feb 2021 22:18:05 |
| User entered 'Female (F)' | (b) (4)<br>Amber Vasquez (b) (4) | 19 Aug 2020 19:15:18 |

US3222220

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:05:20

[Ethnicity](#)

| Audit  | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)      | 27 Apr 2021 13:56:47 |
| User signature succeeded.                                      | Bruce Rankin (b) (4)  | 19 Feb 2021 22:18:05 |
| User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)' | Amber Vasquez (b) (4) | 19 Aug 2020 19:15:18 |



US3222220

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:05:20

White

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 27 Apr 2021 13:56:47 |
| User signature succeeded. | Bruce Rankin (b) (4)  | 19 Feb 2021 22:18:05 |
| User entered 'I'          | Amber Vasquez (b) (4) | 19 Aug 2020 19:15:18 |

US3222220

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:05:20

Black

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 27 Apr 2021 13:56:47 |
| User signature succeeded. | Bruce Rankin (b) (4)  | 19 Feb 2021 22:18:05 |
| User entered '0'          | Amber Vasquez (b) (4) | 19 Aug 2020 19:15:18 |

US3222220

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:05:20

[Asian](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 27 Apr 2021 13:56:47 |
| User signature succeeded. | Bruce Rankin (b) (4)  | 19 Feb 2021 22:18:05 |
| User entered '0'          | Amber Vasquez (b) (4) | 19 Aug 2020 19:15:18 |

US3222220

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:05:20

[American Indian or Alaska Native](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 13:56:47 |
| User signature succeeded. | Bruce Rankin (b) (4)             | 19 Feb 2021 22:18:05 |
| User entered '0'          | (b) (4)<br>Amber Vasquez (b) (4) | 19 Aug 2020 19:15:18 |

US3222220

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:05:20

[Native Hawaiian or other Pacific Islander](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 27 Apr 2021 13:56:47 |
| User signature succeeded. | Bruce Rankin (b) (4)  | 19 Feb 2021 22:18:05 |
| User entered '0'          | Amber Vasquez (b) (4) | 19 Aug 2020 19:15:18 |

US3222220

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:05:20

[Other](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 13:56:47 |
| User signature succeeded. | Bruce Rankin (b) (4)             | 19 Feb 2021 22:18:05 |
| User entered '0'          | (b) (4)<br>Amber Vasquez (b) (4) | 19 Aug 2020 19:15:18 |

US3222220

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:05:20

If race is Other, specify

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 27 Apr 2021 13:56:47 |
| User signature succeeded. | Bruce Rankin (b) (4)  | 19 Feb 2021 22:18:05 |
| User entered empty.       | (b) (4)               |                      |
|                           | Amber Vasquez (b) (4) | 19 Aug 2020 19:15:18 |
|                           | (b) (4)               |                      |

US3222220

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:05:20

Unknown

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 27 Apr 2021 13:56:47 |
| User signature succeeded. | Bruce Rankin (b) (4)  | 19 Feb 2021 22:18:05 |
| User entered '0'          | Amber Vasquez (b) (4) | 19 Aug 2020 19:15:18 |



US3222220

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:05:20

[Not reported](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 27 Apr 2021 13:56:47 |
| User signature succeeded. | Bruce Rankin (b) (4)  | 19 Feb 2021 22:18:05 |
| User entered '0'          | Amber Vasquez (b) (4) | 19 Aug 2020 19:15:18 |

US3222220

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:05:20

Date of Informed Consent (*dd MMM yyyy*)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)         | 27 Apr 2021 13:56:47 |
| User signature succeeded.  | Bruce Rankin (b) (4)     | 19 Feb 2021 22:18:05 |
| User entered '19 Aug 2020' | Jennifer Dittman (b) (4) | 19 Aug 2020 15:09:34 |

US3222220

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:05:20

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

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 27 Apr 2021 13:56:47 |
| User entered 'Aug 2020' | System           | 19 Aug 2020 15:09:34 |

US3222220

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:05:20

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 13:56:47 |
| User entered '2020' | System           | 19 Aug 2020 15:09:34 |

US3222220

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:05:20

[Protocol Version](#)

| Audit                          | User                     | Time (GMT)           |
|--------------------------------|--------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)         | 27 Apr 2021 13:56:47 |
| User signature succeeded.      | Bruce Rankin (b) (4)     | 19 Feb 2021 22:18:05 |
| User entered 'Amendment 2 (2)' | Jennifer Dittman (b) (4) | 19 Aug 2020 15:09:34 |

US3222220

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:05:20

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

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 27 Apr 2021 13:56:47 |
| User signature succeeded. | Bruce Rankin (b) (4)     | 19 Feb 2021 22:18:05 |
| User entered 'Yes (Y)'    | Jennifer Dittman (b) (4) | 19 Aug 2020 15:09:34 |

US3222220

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:05:20

If No, indicate reason for screen fail

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 27 Apr 2021 13:56:47 |
| User signature succeeded. | Bruce Rankin (b) (4)     | 19 Feb 2021 22:18:05 |
| User entered empty.       | Jennifer Dittman (b) (4) | 19 Aug 2020 15:09:34 |

US3222220

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:05:20

If reason for screen fail is Other, specify

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 27 Apr 2021 13:56:47 |
| User signature succeeded. | Bruce Rankin (b) (4)     | 19 Feb 2021 22:18:05 |
| User entered empty.       | Jennifer Dittman (b) (4) | 19 Aug 2020 15:09:34 |



US3222220

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:05:20

[Was this participant screened previously?](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 27 Apr 2021 13:56:47 |
| User signature succeeded. | Bruce Rankin (b) (4)     | 19 Feb 2021 22:18:05 |
| User entered 'No (N)'     | Jennifer Dittman (b) (4) | 19 Aug 2020 15:09:34 |

US3222220

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:05:20

[If Yes, previous participant number](#)

| Audit                     | User  | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                            | 27 Apr 2021 13:56:47 |
| User signature succeeded. | Bruce Rankin (b) (4)                        | 19 Feb 2021 22:18:05 |
| User entered empty.       | (b) (4)<br>RWS_ENDPOINT<br>ENDPOINT (b) (4) | 19 Aug 2020 15:04:33 |

US3222220

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:05:20

[Enrollment Trigger](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 13:56:47 |
| User entered '1'  | System           | 19 Aug 2020 15:09:34 |

US3222220

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 16:05:20

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

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 27 Apr 2021 13:56:47 |
| User signature succeeded. | Bruce Rankin (b) (4)     | 19 Feb 2021 22:18:05 |
| User entered 'Yes (Y)'    | Jennifer Dittman (b) (4) | 19 Aug 2020 15:09:09 |

US3222220

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 16:05:20

[Were any significant conditions reported?](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 13:56:47 |
| User signature succeeded. | Bruce Rankin (b) (4)             | 19 Feb 2021 22:18:05 |
| User entered 'Yes (Y)'    | (b) (4)<br>Amber Vasquez (b) (4) | 19 Aug 2020 19:15:42 |

US3222220

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:05:20

Condition

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)      | 27 Apr 2021 13:56:47 |
| User signature succeeded.   | Bruce Rankin (b) (4)  | 19 Feb 2021 22:18:05 |
| User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Allergic reaction to analgesics - version MedDRA\\23.0. | Coder Import (b) (4)  | 04 Sep 2020 10:43:34 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.   | Coder Import (b) (4)  | 04 Sep 2020 10:43:34 |
| User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0.                    | Coder Import (b) (4)  | 19 Aug 2020 21:06:13 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.   | Coder Import (b) (4)  | 19 Aug 2020 21:06:13 |
| Data point term sent to Coder   | System                | 19 Aug 2020 19:17:09 |
| User entered 'Allergies, Tramadol'  | Amber Vasquez (b) (4) | 19 Aug 2020 19:16:41 |

US3222220

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:05:20

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

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 27 Apr 2021 13:56:47 |
| User signature succeeded. | Bruce Rankin (b) (4)  | 19 Feb 2021 22:18:05 |
| User entered empty.       | Amber Vasquez (b) (4) | 19 Aug 2020 19:16:41 |

US3222220

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:05:20

[Start date completely unknown](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 13:56:47 |
| User signature succeeded. | Bruce Rankin (b) (4)             | 19 Feb 2021 22:18:05 |
| User entered 'I'          | (b) (4)<br>Amber Vasquez (b) (4) | 19 Aug 2020 19:16:41 |



US3222220

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:05:20

[Condition ongoing at study entry](#)

| Audit  | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)      | 27 Apr 2021 13:56:47 |
| User signature succeeded.  | Bruce Rankin (b) (4)  | 19 Feb 2021 22:18:05 |
| User closed query 'Data is required. Please complete.' (Site from System).             | (b) (4)               | 19 Aug 2020 19:16:59 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                | 19 Aug 2020 19:16:59 |
| User entered 'Yes (Y)' reason for change: Data Entry Error                             | Amber Vasquez (b) (4) | 19 Aug 2020 19:16:59 |
| User opened query 'Data is required. Please complete.' (Site from System).             | (b) (4)               | 19 Aug 2020 19:16:41 |
| User entered empty.  | System                | 19 Aug 2020 19:16:41 |
|  | Amber Vasquez (b) (4) | 19 Aug 2020 19:16:41 |
|  | (b) (4)               |                      |

US3222220

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:05:20

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

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 13:56:47 |
| User signature succeeded. | Bruce Rankin (b) (4)             | 19 Feb 2021 22:18:05 |
| User entered empty.       | (b) (4)<br>Amber Vasquez (b) (4) | 19 Aug 2020 19:16:41 |

US3222220

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:05:20

[Stop date completely unknown](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 13:56:47 |
| User signature succeeded. | Bruce Rankin (b) (4)             | 19 Feb 2021 22:18:05 |
| User entered '0'          | (b) (4)<br>Amber Vasquez (b) (4) | 19 Aug 2020 19:16:41 |

US3222220

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:05:20

Start Month and Year (derived)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 13:56:47 |
| User entered empty. | System           | 19 Aug 2020 19:16:41 |

US3222220

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:05:20

Start Year (derived)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 13:56:47 |
| User entered empty. | System           | 19 Aug 2020 19:16:41 |

US3222220

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:05:20

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 13:56:47 |
| User entered empty. | System           | 19 Aug 2020 19:16:41 |

US3222220

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:05:20

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 13:56:47 |
| User entered empty. | System           | 19 Aug 2020 19:16:41 |

US3222220

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:05:20

[Condition](#)

| Audit  | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)      | 27 Apr 2021 13:56:47 |
| User signature succeeded.  | Bruce Rankin (b) (4)  | 19 Feb 2021 22:18:05 |
| User coded data point as SOC: Social circumstances, HLT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0. | Coder Import (b) (4)  | 05 Sep 2020 17:46:39 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.   | Coder Import (b) (4)  | 05 Sep 2020 17:46:39 |
| Data point term sent to Coder  | System                | 05 Sep 2020 17:46:02 |
| User entered 'Postmenopausal'  | Amber Vasquez (b) (4) | 05 Sep 2020 17:45:24 |



US3222220

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:05:20

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

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 27 Apr 2021 13:56:47 |
| User signature succeeded. | Bruce Rankin (b) (4)  | 19 Feb 2021 22:18:05 |
| User entered empty.       | Amber Vasquez (b) (4) | 05 Sep 2020 17:45:24 |

US3222220

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:05:20

[Start date completely unknown](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 27 Apr 2021 13:56:47 |
| User signature succeeded. | Bruce Rankin (b) (4)  | 19 Feb 2021 22:18:05 |
| User entered 'I'          | Amber Vasquez (b) (4) | 05 Sep 2020 17:45:24 |

US3222220

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:05:20

[Condition ongoing at study entry](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 13:56:47 |
| User signature succeeded. | Bruce Rankin (b) (4)             | 19 Feb 2021 22:18:05 |
| User entered 'Yes (Y)'    | (b) (4)<br>Amber Vasquez (b) (4) | 05 Sep 2020 17:45:24 |

US3222220

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:05:20

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

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 27 Apr 2021 13:56:47 |
| User signature succeeded. | Bruce Rankin (b) (4)  | 19 Feb 2021 22:18:05 |
| User entered empty.       | Amber Vasquez (b) (4) | 05 Sep 2020 17:45:24 |

US3222220

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:05:20

[Stop date completely unknown](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 27 Apr 2021 13:56:47 |
| User signature succeeded. | Bruce Rankin (b) (4)  | 19 Feb 2021 22:18:05 |
| User entered '0'          | Amber Vasquez (b) (4) | 05 Sep 2020 17:45:24 |

US3222220

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:05:20

Start Month and Year (derived)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 13:56:47 |
| User entered empty. | System           | 05 Sep 2020 17:45:24 |

US3222220

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:05:20

Start Year (derived)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 13:56:47 |
| User entered empty. | System           | 05 Sep 2020 17:45:24 |

US3222220

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:05:20

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 13:56:47 |
| User entered empty. | System           | 05 Sep 2020 17:45:24 |



US3222220

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:05:20

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 13:56:47 |
| User entered empty. | System           | 05 Sep 2020 17:45:24 |

US3222220

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:05:20

[Condition](#)

| Audit  | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)      | 27 Apr 2021 13:56:47 |
| User signature succeeded.  | Bruce Rankin (b) (4)  | 19 Feb 2021 22:18:05 |
| User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastrooesophageal reflux disease, LLT: GERD - version MedDRA\\23.0. | Coder Import (b) (4)  | 19 Dec 2020 12:53:52 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.   | Coder Import (b) (4)  | 19 Dec 2020 12:53:52 |
| Data point term sent to Coder  | System                | 19 Dec 2020 12:53:25 |
| User entered 'GERD'  | Albert Garcia (b) (4) | 19 Dec 2020 12:52:44 |

US3222220

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:05:20

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

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 27 Apr 2021 13:56:47 |
| User signature succeeded.  | Bruce Rankin (b) (4)  | 19 Feb 2021 22:18:05 |
| User entered 'UN UNK 2019' | Albert Garcia (b) (4) | 19 Dec 2020 12:52:44 |

US3222220

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:05:20

[Start date completely unknown](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 27 Apr 2021 13:56:47 |
| User signature succeeded. | Bruce Rankin (b) (4)  | 19 Feb 2021 22:18:05 |
| User entered '0'          | Albert Garcia (b) (4) | 19 Dec 2020 12:52:44 |

US3222220

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:05:20

[Condition ongoing at study entry](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 27 Apr 2021 13:56:47 |
| User signature succeeded. | Bruce Rankin (b) (4)  | 19 Feb 2021 22:18:05 |
| User entered 'Yes (Y)'    | Albert Garcia (b) (4) | 19 Dec 2020 12:52:44 |

US3222220

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:05:20

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

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 27 Apr 2021 13:56:47 |
| User signature succeeded. | Bruce Rankin (b) (4)  | 19 Feb 2021 22:18:05 |
| User entered empty.       | Albert Garcia (b) (4) | 19 Dec 2020 12:52:44 |

US3222220

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:05:20

[Stop date completely unknown](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 27 Apr 2021 13:56:47 |
| User signature succeeded. | Bruce Rankin (b) (4)  | 19 Feb 2021 22:18:05 |
| User entered '0'          | Albert Garcia (b) (4) | 19 Dec 2020 12:52:44 |

US3222220

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:05:20

Start Month and Year (derived)

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 27 Apr 2021 13:56:47 |
| User entered 'Jan 2019' | System           | 19 Dec 2020 12:52:44 |



US3222220

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:05:20

Start Year (derived)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 13:56:47 |
| User entered '2019' | System           | 19 Dec 2020 12:52:44 |

US3222220

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:05:20

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 13:56:47 |
| User entered empty. | System           | 19 Dec 2020 12:52:44 |

US3222220

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:05:20

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 13:56:47 |
| User entered empty. | System           | 19 Dec 2020 12:52:44 |

US3222220

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:20

[Were vital signs assessed?](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 13:56:47 |
| User signature succeeded. | Bruce Rankin (b) (4)             | 19 Feb 2021 22:18:05 |
| User entered 'Yes (Y)'    | (b) (4)<br>Amber Vasquez (b) (4) | 19 Aug 2020 19:18:11 |

US3222220

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:20

Date of assessment (*dd MMM yyyy*)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                 | 27 Apr 2021 13:56:47 |
| User signature succeeded.  | Bruce Rankin (b) (4)             | 19 Feb 2021 22:18:05 |
| User entered '19 Aug 2020' | (b) (4)<br>Amber Vasquez (b) (4) | 19 Aug 2020 19:18:11 |

US3222220

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:20

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

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 27 Apr 2021 13:56:47 |
| User signature succeeded. | Bruce Rankin (b) (4)  | 19 Feb 2021 22:18:05 |
| User entered '11:30'      | Amber Vasquez (b) (4) | 19 Aug 2020 19:18:11 |

US3222220

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:20

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

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Apr 2021 13:56:47 |
| User entered '19 Aug 2020 11:30' | System           | 19 Aug 2020 19:18:11 |

US3222220

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:20

Height (xxx.x)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 13:56:47 |
| User signature succeeded. | Bruce Rankin (b) (4)             | 19 Feb 2021 22:18:05 |
| User entered '165.1' cm   | (b) (4)<br>Amber Vasquez (b) (4) | 19 Aug 2020 19:18:11 |
| DataPoint set to visible. | (b) (4)<br>System                | 19 Aug 2020 15:09:34 |



US3222220

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:20

Weight (xxx.x)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 13:56:47 |
| User signature succeeded. | Bruce Rankin (b) (4)             | 19 Feb 2021 22:18:05 |
| User entered '54.4' kg    | (b) (4)<br>Amber Vasquez (b) (4) | 19 Aug 2020 19:18:11 |
| DataPoint set to visible. | (b) (4)<br>System                | 19 Aug 2020 15:09:34 |

US3222220

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:20

BMI (xxx.x)

| Audit                                      | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6) | 27 Apr 2021 13:56:47 |
| Amendment Manager: User entered '19.95744' | System           | 17 Sep 2020 00:13:51 |
| User entered '20.0'                        | System           | 19 Aug 2020 19:18:11 |
| DataPoint set to visible.                  | System           | 19 Aug 2020 15:09:34 |

US3222220

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:20

[BMI units](#)

| Audit                     | User             | Time (GMT)           |
|---------------------------|------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6) | 27 Apr 2021 13:56:47 |
| User entered 'kg/m2'      | System           | 19 Aug 2020 19:18:11 |
| DataPoint set to visible. | System           | 19 Aug 2020 15:09:34 |

US3222220

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:20

Temperature (xxx.x)

| Audit   | User                             | Time (GMT)           |
|---|----------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                 | 27 Apr 2021 13:56:47 |
| User signature succeeded.   | Bruce Rankin (b) (4)             | 19 Feb 2021 22:18:05 |
| User closed query 'Per CDM: As per CCG Pages 15-16, 'ND' should be entered in TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at Screening Visit. Please update accordingly.' (Site from DM).             | (b) (4)<br>(b) (4), (b) (6)      | 21 Sep 2020 17:19:57 |
| Query 'Per CDM: As per CCG Pages 15-16, 'ND' should be entered in TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at Screening Visit. Please update accordingly.' answered with 'UPDATED' (Site from DM). | Albert Garcia (b) (4)<br>(b) (4) | 17 Sep 2020 15:29:33 |
| User entered missing code ND - Not Done; reason for change Data Entry Error   | Albert Garcia (b) (4)<br>(b) (4) | 17 Sep 2020 15:29:28 |
| User opened query 'Per CDM: As per CCG Pages 15-16, 'ND' should be entered in TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at Screening Visit. Please update accordingly.' (Site from DM).             | (b) (4), (b) (6)                 | 15 Sep 2020 14:47:40 |
| User entered '36.9' C   | Amber Vasquez (b) (4)<br>(b) (4) | 19 Aug 2020 19:18:11 |

US3222220

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:20

[Route of measurement](#)

| Audit  | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| Data hard locked.                                      | (b) (4), (b) (6)      | 27 Apr 2021 13:56:47 |
| User signature succeeded.                              | Bruce Rankin (b) (4)  | 19 Feb 2021 22:18:05 |
| User entered empty; reason for change Data Entry Error | Albert Garcia (b) (4) | 17 Sep 2020 15:29:28 |
| User entered 'Oral (Oral)'                             | Amber Vasquez (b) (4) | 19 Aug 2020 19:18:11 |

US3222220

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:20

[If Other, specify](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 27 Apr 2021 13:56:47 |
| User signature succeeded. | Bruce Rankin (b) (4)  | 19 Feb 2021 22:18:05 |
| User entered empty.       | (b) (4)               |                      |
|                           | Amber Vasquez (b) (4) | 19 Aug 2020 19:18:11 |
|                           | (b) (4)               |                      |

US3222220

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:20

[Pulse \(xxx\)](#)

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)      | 27 Apr 2021 13:56:47 |
| User signature succeeded.   | Bruce Rankin (b) (4)  | 19 Feb 2021 22:18:05 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4)               | 17 Sep 2020 15:29:28 |
| User entered '89'   | Albert Garcia (b) (4) | 17 Sep 2020 15:29:28 |
|   | (b) (4)               |                      |
|   | Amber Vasquez (b) (4) | 19 Aug 2020 19:18:11 |
|   | (b) (4)               |                      |

US3222220

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:20

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Apr 2021 13:56:47 |
| User entered 'bpm' | System           | 19 Aug 2020 19:18:11 |



US3222220

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:20

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

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)      | 27 Apr 2021 13:56:47 |
| User signature succeeded.   | Bruce Rankin (b) (4)  | 19 Feb 2021 22:18:05 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4)               | 17 Sep 2020 15:29:28 |
| User entered '16'   | Albert Garcia (b) (4) | 17 Sep 2020 15:29:28 |
|   | (b) (4)               |                      |
|   | Amber Vasquez (b) (4) | 19 Aug 2020 19:18:11 |
|   | (b) (4)               |                      |

US3222220

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:20

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 27 Apr 2021 13:56:47 |
| User entered 'breaths/min' | System           | 19 Aug 2020 19:18:11 |

US3222220

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:20

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

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)      | 27 Apr 2021 13:56:47 |
| User signature succeeded.   | Bruce Rankin (b) (4)  | 19 Feb 2021 22:18:05 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4)               | 17 Sep 2020 15:29:28 |
| User entered '122'  | Albert Garcia (b) (4) | 17 Sep 2020 15:29:28 |
|   | (b) (4)               |                      |
|   | Amber Vasquez (b) (4) | 19 Aug 2020 19:18:11 |
|   | (b) (4)               |                      |

US3222220

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:20

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 13:56:47 |
| User entered 'mmHg' | System           | 19 Aug 2020 19:18:11 |

US3222220

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:20

Diastolic Blood Pressure (xxx)

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)      | 27 Apr 2021 13:56:47 |
| User signature succeeded.   | Bruce Rankin (b) (4)  | 19 Feb 2021 22:18:05 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4)               | 17 Sep 2020 15:29:28 |
| User entered '97'   | Albert Garcia (b) (4) | 19 Aug 2020 19:18:11 |
|   | (b) (4)               |                      |

US3222220

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:20

Diastolic Blood Pressure units

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 13:56:47 |
| User entered 'mmHg' | System           | 19 Aug 2020 19:18:11 |

US3222220

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:20

[Height \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 13:56:47 |
|                   |                  |                      |

US3222220

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:20

Weight (derived)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 13:56:47 |



US3222220

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:05:20

[Was the physical examination performed?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 27 Apr 2021 13:56:47 |
| User signature succeeded. | Bruce Rankin (b) (4)  | 19 Feb 2021 22:18:05 |
| User entered 'Yes (Y)'    | Amber Vasquez (b) (4) | 19 Aug 2020 19:19:17 |

US3222220

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:05:20

Date of examination (*dd MMM yyyy*)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 27 Apr 2021 13:56:47 |
| User signature succeeded.  | Bruce Rankin (b) (4)  | 19 Feb 2021 22:18:05 |
| User entered '19 Aug 2020' | Amber Vasquez (b) (4) | 19 Aug 2020 19:19:17 |

US3222220

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:05:20

Date of assessment (*dd MMM yyyy*)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 27 Apr 2021 13:56:47 |
| User signature succeeded.  | Bruce Rankin (b) (4)  | 19 Feb 2021 22:18:05 |
| User entered '19 Aug 2020' | Amber Vasquez (b) (4) | 19 Aug 2020 19:19:53 |

US3222220

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:05:20

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

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 13:56:47 |
| User signature succeeded. | Bruce Rankin (b) (4)             | 19 Feb 2021 22:18:05 |
| User entered 'No (N)'     | (b) (4)<br>Amber Vasquez (b) (4) | 19 Aug 2020 19:19:53 |

US3222220

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:05:20

If No, what is the reason?

| Audit  | User                             | Time (GMT)           |
|--|----------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                 | 27 Apr 2021 13:56:47 |
| User signature succeeded.  | Bruce Rankin (b) (4)             | 19 Feb 2021 22:18:05 |
| User closed query 'Per DM CLR: Note,If No, what is the reason?= Surgically sterile; however no corresponding procedure is recorded in MH ecrf. Please update MH ecrf to include the procedure and the medical condition associated with this procedure in MH ecrf if applicable. Review and update as appropriate.<br>' (Site from DM).                | (b) (4)<br>(b) (4), (b) (6)      | 21 Sep 2020 17:20:21 |
| Query 'Per DM CLR: Note,If No, what is the reason?= Surgically sterile; however no corresponding procedure is recorded in MH ecrf. Please update MH ecrf to include the procedure and the medical condition associated with this procedure in MH ecrf if applicable. Review and update as appropriate.<br>' answered with 'MH updated' (Site from DM). | Amber Vasquez (b) (4)<br>(b) (4) | 05 Sep 2020 17:44:59 |
| User entered 'Post-menopausal (POST-MENOPAUSAL)' reason for change: Data Entry Error   | Amber Vasquez (b) (4)<br>(b) (4) | 05 Sep 2020 17:44:46 |
| User opened query 'Per DM CLR: Note,If No, what is the reason?= Surgically sterile; however no corresponding procedure is recorded in MH ecrf. Please update MH ecrf to include the procedure and the medical condition associated with this procedure in MH ecrf if applicable. Review and update as appropriate.<br>' (Site from DM).                | (b) (4), (b) (6)                 | 26 Aug 2020 07:44:09 |
| User entered 'Surgically sterile (SURGICALLY STERILE)'   | Amber Vasquez (b) (4)<br>(b) (4) | 19 Aug 2020 19:19:53 |

US3222220

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:05:20

If Partner medically sterile or Other, specify

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 13:56:47 |
| User signature succeeded. | Bruce Rankin (b) (4)             | 19 Feb 2021 22:18:05 |
| User entered empty.       | (b) (4)<br>Amber Vasquez (b) (4) | 19 Aug 2020 19:19:53 |

US3222220

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:05:20

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

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 13:56:47 |
| User signature succeeded. | Bruce Rankin (b) (4)             | 19 Feb 2021 22:18:05 |
| User entered empty.       | (b) (4)<br>Amber Vasquez (b) (4) | 19 Aug 2020 19:19:53 |

US3222220

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:05:20

Date of surgery unknown

| Audit  | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| Data hard locked.                                    | (b) (4), (b) (6)      | 27 Apr 2021 13:56:47 |
| User signature succeeded.                            | Bruce Rankin (b) (4)  | 19 Feb 2021 22:18:05 |
| User entered '0' reason for change: Data Entry Error | (b) (4)               |                      |
|  | Amber Vasquez (b) (4) | 05 Sep 2020 17:44:46 |
| User entered '1'                                     | (b) (4)               |                      |
|  | Amber Vasquez (b) (4) | 19 Aug 2020 19:19:53 |
|  | (b) (4)               |                      |



US3222220

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:05:20

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

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 27 Apr 2021 13:56:47 |
| User signature succeeded. | Bruce Rankin (b) (4)  | 19 Feb 2021 22:18:05 |
| User entered empty.       | Amber Vasquez (b) (4) | 19 Aug 2020 19:19:53 |

US3222220

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:05:20

Date of last menstruation unknown

| Audit  | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| Data hard locked.                                    | (b) (4), (b) (6)      | 27 Apr 2021 13:56:47 |
| User signature succeeded.                            | Bruce Rankin (b) (4)  | 19 Feb 2021 22:18:05 |
| User entered '1' reason for change: Data Entry Error | (b) (4)               |                      |
|  | Amber Vasquez (b) (4) | 05 Sep 2020 17:44:46 |
| User entered '0'                                     | (b) (4)               |                      |
|  | Amber Vasquez (b) (4) | 19 Aug 2020 19:19:53 |
|  | (b) (4)               |                      |

US3222220

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:20

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

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 13:56:47 |
| User signature succeeded. | Bruce Rankin (b) (4)             | 19 Feb 2021 22:18:05 |
| User entered 'No (N)'     | (b) (4)<br>Amber Vasquez (b) (4) | 19 Aug 2020 19:20:54 |

US3222220

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:20

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

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 13:56:47 |
| User signature succeeded. | Bruce Rankin (b) (4)             | 19 Feb 2021 22:18:05 |
| User entered 'No (N)'     | (b) (4)<br>Amber Vasquez (b) (4) | 19 Aug 2020 19:20:54 |

US3222220

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:20

**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)      | 27 Apr 2021 13:56:47 |
| User signature succeeded. | Bruce Rankin (b) (4)  | 19 Feb 2021 22:18:05 |
| User entered 'No (N)'     | Amber Vasquez (b) (4) | 19 Aug 2020 19:20:54 |

US3222220

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:20

**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)      | 27 Apr 2021 13:56:47 |
| User signature succeeded. | Bruce Rankin (b) (4)  | 19 Feb 2021 22:18:05 |
| User entered 'No (N)'     | Amber Vasquez (b) (4) | 19 Aug 2020 19:20:54 |

US3222220

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:20

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

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 27 Apr 2021 13:56:47 |
| User signature succeeded. | Bruce Rankin (b) (4)  | 19 Feb 2021 22:18:05 |
| User entered 'No (N)'     | Amber Vasquez (b) (4) | 19 Aug 2020 19:20:54 |

US3222220

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:20

[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)      | 27 Apr 2021 13:56:47 |
| User signature succeeded. | Bruce Rankin (b) (4)  | 19 Feb 2021 22:18:05 |
| User entered 'No (N)'     | Amber Vasquez (b) (4) | 19 Aug 2020 19:20:54 |



US3222220

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:20

**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)      | 27 Apr 2021 13:56:47 |
| User signature succeeded. | Bruce Rankin (b) (4)  | 19 Feb 2021 22:18:05 |
| User entered 'No (N)'     | Amber Vasquez (b) (4) | 19 Aug 2020 19:20:54 |

US3222220

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:20

**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)      | 27 Apr 2021 13:56:47 |
| User signature succeeded. | Bruce Rankin (b) (4)  | 19 Feb 2021 22:18:05 |
| User entered 'No (N)'     | Amber Vasquez (b) (4) | 19 Aug 2020 19:20:54 |

US3222220

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:20

[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)                 | 27 Apr 2021 13:56:47 |
| User signature succeeded. | Bruce Rankin (b) (4)             | 19 Feb 2021 22:18:05 |
| User entered 'No (N)'     | (b) (4)<br>Amber Vasquez (b) (4) | 19 Aug 2020 19:20:54 |

US3222220

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:20

**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)      | 27 Apr 2021 13:56:47 |
| User signature succeeded. | Bruce Rankin (b) (4)  | 19 Feb 2021 22:18:05 |
| User entered 'No (N)'     | Amber Vasquez (b) (4) | 19 Aug 2020 19:20:54 |

US3222220

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:20

**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)      | 27 Apr 2021 13:56:47 |
| User signature succeeded. | Bruce Rankin (b) (4)  | 19 Feb 2021 22:18:05 |
| User entered 'No (N)'     | Amber Vasquez (b) (4) | 19 Aug 2020 19:20:54 |

US3222220

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:20

Other

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 27 Apr 2021 13:56:47 |
| User signature succeeded. | Bruce Rankin (b) (4)  | 19 Feb 2021 22:18:05 |
| User entered 'Yes (Y)'    | (b) (4)               |                      |
|                           | Amber Vasquez (b) (4) | 19 Aug 2020 19:20:54 |
|                           | (b) (4)               |                      |

US3222220

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:20

[Specify](#)

| Audit                         | User                  | Time (GMT)           |
|-------------------------------|-----------------------|----------------------|
| Data hard locked.             | (b) (4), (b) (6)      | 27 Apr 2021 13:56:47 |
| User signature succeeded.     | Bruce Rankin (b) (4)  | 19 Feb 2021 22:18:05 |
| User entered 'Indigent care.' | (b) (4)               |                      |
|                               | Amber Vasquez (b) (4) | 19 Aug 2020 19:20:54 |
|                               | (b) (4)               |                      |

US3222220

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:20

No Risk Identified

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 13:56:47 |
| User signature succeeded. | Bruce Rankin (b) (4)             | 19 Feb 2021 22:18:05 |
| User entered 'I'          | (b) (4)<br>Amber Vasquez (b) (4) | 19 Aug 2020 19:20:54 |



US3222220

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:20

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

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 27 Apr 2021 13:56:47 |
| User signature succeeded. | Bruce Rankin (b) (4)  | 19 Feb 2021 22:18:05 |
| User entered '0'          | Amber Vasquez (b) (4) | 19 Aug 2020 19:20:54 |

US3222220

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:20

**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)      | 27 Apr 2021 13:56:47 |
| User signature succeeded. | Bruce Rankin (b) (4)  | 19 Feb 2021 22:18:05 |
| User entered '0'          | Amber Vasquez (b) (4) | 19 Aug 2020 19:20:54 |

US3222220

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:20

[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)                 | 27 Apr 2021 13:56:47 |
| User signature succeeded. | Bruce Rankin (b) (4)             | 19 Feb 2021 22:18:05 |
| User entered '0'          | (b) (4)<br>Amber Vasquez (b) (4) | 19 Aug 2020 19:20:54 |

US3222220

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:20

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)      | 27 Apr 2021 13:56:47 |
| User signature succeeded. | Bruce Rankin (b) (4)  | 19 Feb 2021 22:18:05 |
| User entered '0'          | Amber Vasquez (b) (4) | 19 Aug 2020 19:20:54 |

US3222220

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:20

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

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 27 Apr 2021 13:56:47 |
| User signature succeeded. | Bruce Rankin (b) (4)  | 19 Feb 2021 22:18:05 |
| User entered '0'          | Amber Vasquez (b) (4) | 19 Aug 2020 19:20:54 |

US3222220

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:20

[Other](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 27 Apr 2021 13:56:47 |
| User signature succeeded. | Bruce Rankin (b) (4)  | 19 Feb 2021 22:18:05 |
| User entered '0'          | Amber Vasquez (b) (4) | 19 Aug 2020 19:20:54 |

US3222220

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:05:20

[Specify](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 27 Apr 2021 13:56:47 |
| User signature succeeded. | Bruce Rankin (b) (4)  | 19 Feb 2021 22:18:05 |
| User entered empty.       | (b) (4)               |                      |
|                           | Amber Vasquez (b) (4) | 19 Aug 2020 19:20:54 |
|                           | (b) (4)               |                      |

US3222220

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:05:20

[Was this visit performed?](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 04 Apr 2021 18:17:07 |
| User signature succeeded. | Bruce Rankin (b) (4)     | 19 Feb 2021 22:18:05 |
| User entered 'Yes (Y)'    | Jennifer Dittman (b) (4) | 19 Aug 2020 15:09:20 |



US3222220

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:05:20

Visit date (dd MMM yyyy)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)         | 04 Apr 2021 18:17:07 |
| User signature succeeded.  | Bruce Rankin (b) (4)     | 19 Feb 2021 22:18:05 |
| User entered '19 Aug 2020' | Jennifer Dittman (b) (4) | 19 Aug 2020 15:09:20 |

US3222220

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:05:20

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

| Audit                          | User                     | Time (GMT)           |
|--------------------------------|--------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)         | 04 Apr 2021 18:17:07 |
| User signature succeeded.      | Bruce Rankin (b) (4)     | 19 Feb 2021 22:18:05 |
| User entered 'Clinic (Clinic)' | Jennifer Dittman (b) (4) | 19 Aug 2020 15:09:20 |

US3222220

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:05:20

[Folder OID](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 04 Apr 2021 18:17:07 |
| User entered 'VISIT1' | System           | 19 Aug 2020 15:09:20 |

US3222220

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:05:20

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

| Audit                      | User  | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                            | 04 Apr 2021 18:17:07 |
| User signature succeeded.  | Bruce Rankin (b) (4)                        | 19 Feb 2021 22:18:05 |
| User entered '19 AUG 2020' | (b) (4)<br>RWS_ENDPOINT<br>ENDPOINT (b) (4) | 19 Aug 2020 15:09:49 |

US3222220

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:05:20

What was the participant's randomization number?

| Audit  | User                             | Time (GMT)           |
|--|----------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                 | 04 Apr 2021 18:17:07 |
| User signature succeeded.  | Bruce Rankin (b) (4)             | 19 Feb 2021 22:18:05 |
| Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System). | (b) (4)<br>System                | 21 Aug 2020 05:32:57 |
| Amendment Manager: Data point set to conformant.   | System                           | 21 Aug 2020 05:32:57 |
| User opened query 'Data entered is non-conformant. Please correct.' (Site from System).                    | System                           | 19 Aug 2020 15:09:49 |
| User entered '105763' (non-conformant).  | RWS_ENDPOINT<br>ENDPOINT (b) (4) | 19 Aug 2020 15:09:49 |

US3222220

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:05:20

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

| Audit   | User  | Time (GMT)           |
|---|---|----------------------|
| Data hard locked.                                     | (b) (4), (b) (6)                            | 04 Apr 2021 18:17:07 |
| User signature succeeded.                             | Bruce Rankin (b) (4)                        | 19 Feb 2021 22:18:05 |
| User entered '>=18 and <65 years and not at risk (1)' | (b) (4)<br>RWS_ENDPOINT<br>ENDPOINT (b) (4) | 19 Aug 2020 15:09:49 |

US3222220

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:05:20

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)         | 04 Apr 2021 18:17:07 |
| User signature succeeded. | Bruce Rankin (b) (4)     | 19 Feb 2021 22:18:05 |
| User entered 'No (N)'     | Jennifer Dittman (b) (4) | 19 Aug 2020 15:12:17 |

US3222220

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:05:20

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)         | 04 Apr 2021 18:17:07 |
| User signature succeeded. | Bruce Rankin (b) (4)     | 19 Feb 2021 22:18:05 |
| User entered 'No (N)'     | Jennifer Dittman (b) (4) | 19 Aug 2020 15:12:17 |



US3222220

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:05:20

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

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 04 Apr 2021 18:17:07 |
| User signature succeeded. | Bruce Rankin (b) (4)     | 19 Feb 2021 22:18:05 |
| User entered 'No (N)'     | Jennifer Dittman (b) (4) | 19 Aug 2020 15:12:17 |

US3222220

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:05:20

Diabetes (Type I, Type 2, or gestational)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 04 Apr 2021 18:17:07 |
| User signature succeeded. | Bruce Rankin (b) (4)     | 19 Feb 2021 22:18:05 |
| User entered 'No (N)'     | Jennifer Dittman (b) (4) | 19 Aug 2020 15:12:17 |

US3222220

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:05:20

[Liver Disease](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 04 Apr 2021 18:17:07 |
| User signature succeeded. | Bruce Rankin (b) (4)     | 19 Feb 2021 22:18:05 |
| User entered 'No (N)'     | Jennifer Dittman (b) (4) | 19 Aug 2020 15:12:17 |

US3222220

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:05:20

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

| Audit  | User                             | Time (GMT)           |
|--|----------------------------------|----------------------|
| Data hard locked.                            | (b) (4), (b) (6)                 | 04 Apr 2021 18:17:07 |
| User signature succeeded.                    | Bruce Rankin (b) (4)             | 19 Feb 2021 22:18:05 |
| User entered 'No (N)'                        | (b) (4)<br>Albert Garcia (b) (4) | 19 Oct 2020 17:23:45 |
| Amendment Manager: DataPoint set to visible. | (b) (4)<br>System                | 19 Sep 2020 10:35:43 |
| Amendment Manager inserted this DataPoint.   | System                           | 19 Sep 2020 01:30:24 |

US3222220

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:05:20

Height

| Audit  | User                             | Time (GMT)           |
|--|----------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                 | 04 Apr 2021 18:17:07 |
| User signature succeeded.  | Bruce Rankin (b) (4)             | 19 Feb 2021 22:18:05 |
| User closed query 'Per CDM: Thanks for your response. Please update the 'HEIGHT' field accordingly.' (Site from DM).   | (b) (4)<br>(b) (4), (b) (6)      | 22 Sep 2020 12:46:43 |
| Query 'Per CDM: Thanks for your response. Please update the 'HEIGHT' field accordingly.' answered by data change (Site from DM).                               | System                           | 17 Sep 2020 15:29:50 |
| User entered missing code ND - Not Done; reason for change Data Entry Error  | Albert Garcia (b) (4)<br>(b) (4) | 17 Sep 2020 15:29:50 |
| User opened query 'Per CDM: Thanks for your response. Please update the 'HEIGHT' field accordingly.' (Site from DM).   | (b) (4), (b) (6)                 | 11 Sep 2020 09:10:42 |
| User closed query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify". (Site from DM).        | (b) (4), (b) (6)                 | 11 Sep 2020 09:10:42 |
| Query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify". answered with 'ND' (Site from DM). | Albert Garcia (b) (4)<br>(b) (4) | 03 Sep 2020 22:48:58 |
| User entered empty; reason for change Data Entry Error   | Albert Garcia (b) (4)<br>(b) (4) | 03 Sep 2020 22:48:50 |
| User opened query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify". (Site from DM).        | (b) (4), (b) (6)                 | 28 Aug 2020 19:49:28 |
| User entered '165.1' cm  | Amber Vasquez (b) (4)<br>(b) (4) | 19 Aug 2020 19:22:50 |

US3222220

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:05:20

Weight

| Audit  | User                             | Time (GMT)           |
|--|----------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                 | 04 Apr 2021 18:17:07 |
| User signature succeeded.  | Bruce Rankin (b) (4)             | 19 Feb 2021 22:18:05 |
| User closed query 'Per CDM: Thanks for your response. Please update the 'WEIGHT' field accordingly.' (Site from DM).   | (b) (4)<br>(b) (4), (b) (6)      | 22 Sep 2020 12:46:46 |
| Query 'Per CDM: Thanks for your response. Please update the 'WEIGHT' field accordingly.' answered by data change (Site from DM).                               | System                           | 17 Sep 2020 15:29:50 |
| User entered missing code ND - Not Done; reason for change Data Entry Error  | Albert Garcia (b) (4)<br>(b) (4) | 17 Sep 2020 15:29:50 |
| User opened query 'Per CDM: Thanks for your response. Please update the 'WEIGHT' field accordingly.' (Site from DM).   | (b) (4), (b) (6)                 | 11 Sep 2020 09:10:52 |
| User closed query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify". (Site from DM).        | (b) (4), (b) (6)                 | 11 Sep 2020 09:10:52 |
| Query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify". answered with 'ND' (Site from DM). | Albert Garcia (b) (4)<br>(b) (4) | 03 Sep 2020 22:49:06 |
| User entered empty; reason for change Data Entry Error   | Albert Garcia (b) (4)<br>(b) (4) | 03 Sep 2020 22:48:50 |
| User opened query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify". (Site from DM).        | (b) (4), (b) (6)                 | 28 Aug 2020 19:49:37 |
| User entered '54.4' kg   | Amber Vasquez (b) (4)<br>(b) (4) | 19 Aug 2020 19:22:50 |

US3222220

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:05:20

Height

| Audit  | User                             | Time (GMT)           |
|--|----------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                 | 04 Apr 2021 18:17:07 |
| User signature succeeded.  | Bruce Rankin (b) (4)             | 19 Feb 2021 22:18:05 |
| User closed query 'Per CDM: Thanks for your response. Please update the 'HEIGHT' field accordingly.' (Site from DM).   | (b) (4)<br>(b) (4), (b) (6)      | 22 Sep 2020 12:46:43 |
| Query 'Per CDM: Thanks for your response. Please update the 'HEIGHT' field accordingly.' answered by data change (Site from DM).                               | System                           | 17 Sep 2020 15:29:50 |
| User entered missing code ND - Not Done; reason for change Data Entry Error  | Albert Garcia (b) (4)<br>(b) (4) | 17 Sep 2020 15:29:50 |
| User opened query 'Per CDM: Thanks for your response. Please update the 'HEIGHT' field accordingly.' (Site from DM).   | (b) (4), (b) (6)                 | 11 Sep 2020 09:10:42 |
| User closed query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify". (Site from DM).        | (b) (4), (b) (6)                 | 11 Sep 2020 09:10:42 |
| Query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify". answered with 'ND' (Site from DM). | Albert Garcia (b) (4)<br>(b) (4) | 03 Sep 2020 22:48:58 |
| User entered empty; reason for change Data Entry Error   | Albert Garcia (b) (4)<br>(b) (4) | 03 Sep 2020 22:48:50 |
| User opened query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify". (Site from DM).        | (b) (4), (b) (6)                 | 28 Aug 2020 19:49:28 |
| User entered '165.1' cm  | Amber Vasquez (b) (4)<br>(b) (4) | 19 Aug 2020 19:22:50 |

US3222220

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:05:20

Weight

| Audit  | User                             | Time (GMT)           |
|--|----------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                 | 04 Apr 2021 18:17:07 |
| User signature succeeded.  | Bruce Rankin (b) (4)             | 19 Feb 2021 22:18:05 |
| User closed query 'Per CDM: Thanks for your response. Please update the 'WEIGHT' field accordingly.' (Site from DM).   | (b) (4)<br>(b) (4), (b) (6)      | 22 Sep 2020 12:46:46 |
| Query 'Per CDM: Thanks for your response. Please update the 'WEIGHT' field accordingly.' answered by data change (Site from DM).                               | System                           | 17 Sep 2020 15:29:50 |
| User entered missing code ND - Not Done; reason for change Data Entry Error  | Albert Garcia (b) (4)<br>(b) (4) | 17 Sep 2020 15:29:50 |
| User opened query 'Per CDM: Thanks for your response. Please update the 'WEIGHT' field accordingly.' (Site from DM).   | (b) (4), (b) (6)                 | 11 Sep 2020 09:10:52 |
| User closed query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify". (Site from DM).        | (b) (4), (b) (6)                 | 11 Sep 2020 09:10:52 |
| Query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify". answered with 'ND' (Site from DM). | Albert Garcia (b) (4)<br>(b) (4) | 03 Sep 2020 22:49:06 |
| User entered empty; reason for change Data Entry Error   | Albert Garcia (b) (4)<br>(b) (4) | 03 Sep 2020 22:48:50 |
| User opened query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify". (Site from DM).        | (b) (4), (b) (6)                 | 28 Aug 2020 19:49:37 |
| User entered '54.4' kg   | Amber Vasquez (b) (4)<br>(b) (4) | 19 Aug 2020 19:22:50 |



US3222220

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:20

[Timepoint](#)

| Audit  | User                             | Time (GMT)           |
|--|----------------------------------|----------------------|
| Data hard locked.                                | (b) (4), (b) (6)                 | 04 Apr 2021 18:17:07 |
| User accepted default value 'Pre-Dose (PREDOSE)' | Amber Vasquez (b) (4)<br>(b) (4) | 19 Aug 2020 19:22:50 |

US3222220

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:20

[Were vital signs assessed?](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 04 Apr 2021 18:17:07 |
| User signature succeeded. | Bruce Rankin (b) (4)             | 19 Feb 2021 22:18:05 |
| User entered 'Yes (Y)'    | (b) (4)<br>Amber Vasquez (b) (4) | 19 Aug 2020 19:22:50 |

US3222220

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:20

Date of assessment (*dd MMM yyyy*)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                 | 04 Apr 2021 18:17:07 |
| User signature succeeded.  | Bruce Rankin (b) (4)             | 19 Feb 2021 22:18:05 |
| User entered '19 Aug 2020' | (b) (4)<br>Amber Vasquez (b) (4) | 19 Aug 2020 19:22:50 |

US3222220

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:20

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

| Audit                     | User  | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                            | 04 Apr 2021 18:17:07 |
| User signature succeeded. | Bruce Rankin (b) (4)                        | 19 Feb 2021 22:18:05 |
| User entered '11:40'      | (b) (4)<br>Amber Vasquez (b) (4)<br>(b) (4) | 19 Aug 2020 19:22:50 |

US3222220

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:20

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

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Apr 2021 18:17:07 |
| User entered '19 Aug 2020 11:40' | System           | 19 Aug 2020 19:22:50 |

US3222220

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:20

Temperature (xxx.x)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 04 Apr 2021 18:17:07 |
| User signature succeeded. | Bruce Rankin (b) (4)             | 19 Feb 2021 22:18:05 |
| User entered '36.0' C     | (b) (4)<br>Amber Vasquez (b) (4) | 19 Aug 2020 19:22:50 |

US3222220

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:20

[Route of measurement](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                 | 04 Apr 2021 18:17:07 |
| User signature succeeded.  | Bruce Rankin (b) (4)             | 19 Feb 2021 22:18:05 |
| User entered 'Oral (Oral)' | (b) (4)<br>Amber Vasquez (b) (4) | 19 Aug 2020 19:22:50 |

US3222220

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:20

[If Other, specify](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 04 Apr 2021 18:17:07 |
| User signature succeeded. | Bruce Rankin (b) (4)             | 19 Feb 2021 22:18:05 |
| User entered empty.       | (b) (4)<br>Amber Vasquez (b) (4) | 19 Aug 2020 19:22:50 |



US3222220

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:20

[Pulse \(xxx\)](#)

| Audit                     | User  | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                            | 04 Apr 2021 18:17:07 |
| User signature succeeded. | Bruce Rankin (b) (4)                        | 19 Feb 2021 22:18:05 |
| User entered '68'         | (b) (4)<br>Amber Vasquez (b) (4)<br>(b) (4) | 19 Aug 2020 19:22:50 |

US3222220

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:20

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Apr 2021 18:17:07 |
| User entered 'bpm' | System           | 19 Aug 2020 19:22:50 |

US3222220

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:20

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

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 04 Apr 2021 18:17:07 |
| User signature succeeded. | Bruce Rankin (b) (4)             | 19 Feb 2021 22:18:05 |
| User entered '18'         | (b) (4)<br>Amber Vasquez (b) (4) | 19 Aug 2020 19:22:50 |

US3222220

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:20

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 04 Apr 2021 18:17:07 |
| User entered 'breaths/min' | System           | 19 Aug 2020 19:22:50 |

US3222220

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:20

Systolic Blood Pressure (xxx)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 04 Apr 2021 18:17:07 |
| User signature succeeded. | Bruce Rankin (b) (4)  | 19 Feb 2021 22:18:05 |
| User entered '140'        | Amber Vasquez (b) (4) | 19 Aug 2020 19:22:50 |

US3222220

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:20

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Apr 2021 18:17:07 |
| User entered 'mmHg' | System           | 19 Aug 2020 19:22:50 |

US3222220

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:20

Diastolic Blood Pressure (xxx)

| Audit                     | User  | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                            | 04 Apr 2021 18:17:07 |
| User signature succeeded. | Bruce Rankin (b) (4)                        | 19 Feb 2021 22:18:05 |
| User entered '90'         | (b) (4)<br>Amber Vasquez (b) (4)<br>(b) (4) | 19 Aug 2020 19:22:50 |

US3222220

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:20

Diastolic Blood Pressure units

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Apr 2021 18:17:07 |
| User entered 'mmHg' | System           | 19 Aug 2020 19:22:50 |



US3222220

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:05:20

Height

| Audit  | User                             | Time (GMT)           |
|--|----------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                 | 04 Apr 2021 18:17:07 |
| User signature succeeded.  | Bruce Rankin (b) (4)             | 19 Feb 2021 22:18:05 |
| User closed query 'Per CDM: Thanks for your response. Please update the 'HEIGHT' field accordingly.' (Site from DM).   | (b) (4)<br>(b) (4), (b) (6)      | 22 Sep 2020 12:46:43 |
| Query 'Per CDM: Thanks for your response. Please update the 'HEIGHT' field accordingly.' answered by data change (Site from DM).                               | System                           | 17 Sep 2020 15:29:50 |
| User entered missing code ND - Not Done; reason for change Data Entry Error  | Albert Garcia (b) (4)<br>(b) (4) | 17 Sep 2020 15:29:50 |
| User opened query 'Per CDM: Thanks for your response. Please update the 'HEIGHT' field accordingly.' (Site from DM).   | (b) (4), (b) (6)                 | 11 Sep 2020 09:10:42 |
| User closed query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify". (Site from DM).        | (b) (4), (b) (6)                 | 11 Sep 2020 09:10:42 |
| Query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify". answered with 'ND' (Site from DM). | Albert Garcia (b) (4)<br>(b) (4) | 03 Sep 2020 22:48:58 |
| User entered empty; reason for change Data Entry Error   | Albert Garcia (b) (4)<br>(b) (4) | 03 Sep 2020 22:48:50 |
| User opened query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify". (Site from DM).        | (b) (4), (b) (6)                 | 28 Aug 2020 19:49:28 |
| User entered '165.1' cm  | Amber Vasquez (b) (4)<br>(b) (4) | 19 Aug 2020 19:22:50 |

US3222220

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:05:20

Weight

| Audit  | User                             | Time (GMT)           |
|--|----------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                 | 04 Apr 2021 18:17:07 |
| User signature succeeded.  | Bruce Rankin (b) (4)             | 19 Feb 2021 22:18:05 |
| User closed query 'Per CDM: Thanks for your response. Please update the 'WEIGHT' field accordingly.' (Site from DM).   | (b) (4)<br>(b) (4), (b) (6)      | 22 Sep 2020 12:46:46 |
| Query 'Per CDM: Thanks for your response. Please update the 'WEIGHT' field accordingly.' answered by data change (Site from DM).                               | System                           | 17 Sep 2020 15:29:50 |
| User entered missing code ND - Not Done; reason for change Data Entry Error  | Albert Garcia (b) (4)<br>(b) (4) | 17 Sep 2020 15:29:50 |
| User opened query 'Per CDM: Thanks for your response. Please update the 'WEIGHT' field accordingly.' (Site from DM).   | (b) (4), (b) (6)                 | 11 Sep 2020 09:10:52 |
| User closed query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify". (Site from DM).        | (b) (4), (b) (6)                 | 11 Sep 2020 09:10:52 |
| Query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify". answered with 'ND' (Site from DM). | Albert Garcia (b) (4)<br>(b) (4) | 03 Sep 2020 22:49:06 |
| User entered empty; reason for change Data Entry Error   | Albert Garcia (b) (4)<br>(b) (4) | 03 Sep 2020 22:48:50 |
| User opened query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify". (Site from DM).        | (b) (4), (b) (6)                 | 28 Aug 2020 19:49:37 |
| User entered '54.4' kg   | Amber Vasquez (b) (4)<br>(b) (4) | 19 Aug 2020 19:22:50 |

US3222220

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:20

[Timepoint](#)

| Audit  | User                             | Time (GMT)           |
|--|----------------------------------|----------------------|
| Data hard locked.                                  | (b) (4), (b) (6)                 | 04 Apr 2021 18:17:07 |
| User accepted default value 'Post-Dose (POSTDOSE)' | Amber Vasquez (b) (4)<br>(b) (4) | 19 Aug 2020 19:22:50 |

US3222220

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:20

[Were vital signs assessed?](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 04 Apr 2021 18:17:07 |
| User signature succeeded. | Bruce Rankin (b) (4)             | 19 Feb 2021 22:18:05 |
| User entered 'Yes (Y)'    | (b) (4)<br>Amber Vasquez (b) (4) | 19 Aug 2020 19:22:50 |

US3222220

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:20

Date of assessment (*dd MMM yyyy*)

| Audit                      | User  | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                            | 04 Apr 2021 18:17:07 |
| User signature succeeded.  | Bruce Rankin (b) (4)                        | 19 Feb 2021 22:18:05 |
| User entered '19 Aug 2020' | (b) (4)<br>Amber Vasquez (b) (4)<br>(b) (4) | 19 Aug 2020 19:22:50 |

US3222220

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:20

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

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)      | 04 Apr 2021 18:17:07 |
| User signature succeeded.   | Bruce Rankin (b) (4)  | 19 Feb 2021 22:18:05 |
| Amendment Manager: Query closed during migrationSystem process because the edit check no longer exists in target version.                                       | (b) (4)               | 21 Aug 2020 05:32:54 |
| User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System). |                       | 19 Aug 2020 19:22:50 |
| User entered '13:40'  | Amber Vasquez (b) (4) | 19 Aug 2020 19:22:50 |
|   | (b) (4)               |                      |

US3222220

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:20

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

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Apr 2021 18:17:07 |
| User entered '19 Aug 2020 13:40' | System           | 19 Aug 2020 19:22:50 |

US3222220

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:20

Temperature (xxx.x)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 04 Apr 2021 18:17:07 |
| User signature succeeded. | Bruce Rankin (b) (4)  | 19 Feb 2021 22:18:05 |
| User entered '36.5' C     | Amber Vasquez (b) (4) | 19 Aug 2020 19:22:50 |



US3222220

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:20

[Route of measurement](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                 | 04 Apr 2021 18:17:07 |
| User signature succeeded.  | Bruce Rankin (b) (4)             | 19 Feb 2021 22:18:05 |
| User entered 'Oral (Oral)' | (b) (4)<br>Amber Vasquez (b) (4) | 19 Aug 2020 19:22:50 |

US3222220

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:20

[If Other, specify](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 04 Apr 2021 18:17:07 |
| User signature succeeded. | Bruce Rankin (b) (4)             | 19 Feb 2021 22:18:05 |
| User entered empty.       | (b) (4)<br>Amber Vasquez (b) (4) | 19 Aug 2020 19:22:50 |

US3222220

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:20

[Pulse \(xxx\)](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 04 Apr 2021 18:17:07 |
| User signature succeeded. | Bruce Rankin (b) (4)             | 19 Feb 2021 22:18:05 |
| User entered '86'         | (b) (4)<br>Amber Vasquez (b) (4) | 19 Aug 2020 19:22:50 |

US3222220

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:20

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Apr 2021 18:17:07 |
| User entered 'bpm' | System           | 19 Aug 2020 19:22:50 |

US3222220

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:20

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

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 04 Apr 2021 18:17:07 |
| User signature succeeded. | Bruce Rankin (b) (4)             | 19 Feb 2021 22:18:05 |
| User entered '16'         | (b) (4)<br>Amber Vasquez (b) (4) | 19 Aug 2020 19:22:50 |

US3222220

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:20

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 04 Apr 2021 18:17:07 |
| User entered 'breaths/min' | System           | 19 Aug 2020 19:22:50 |

US3222220

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:20

Systolic Blood Pressure (xxx)

| Audit                     | User  | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                            | 04 Apr 2021 18:17:07 |
| User signature succeeded. | Bruce Rankin (b) (4)                        | 19 Feb 2021 22:18:05 |
| User entered '114'        | (b) (4)<br>Amber Vasquez (b) (4)<br>(b) (4) | 19 Aug 2020 19:22:50 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:20

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Apr 2021 18:17:07 |
| User entered 'mmHg' | System           | 19 Aug 2020 19:22:50 |



US3222220

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:20

Diastolic Blood Pressure (xxx)

| Audit                     | User  | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                            | 04 Apr 2021 18:17:07 |
| User signature succeeded. | Bruce Rankin (b) (4)                        | 19 Feb 2021 22:18:05 |
| User entered '80'         | (b) (4)<br>Amber Vasquez (b) (4)<br>(b) (4) | 19 Aug 2020 19:22:50 |

US3222220

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:20

Diastolic Blood Pressure units

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Apr 2021 18:17:07 |
| User entered 'mmHg' | System           | 19 Aug 2020 19:22:50 |

US3222220

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:05:20

[Was the physical examination performed?](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 04 Apr 2021 18:17:07 |
| User signature succeeded. | Bruce Rankin (b) (4)             | 19 Feb 2021 22:18:05 |
| User entered 'Yes (Y)'    | (b) (4)<br>Amber Vasquez (b) (4) | 19 Aug 2020 19:23:15 |

US3222220

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:05:20

Date of examination (*dd MMM yyyy*)

| Audit                      | User  | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                            | 04 Apr 2021 18:17:07 |
| User signature succeeded.  | Bruce Rankin (b) (4)                        | 19 Feb 2021 22:18:05 |
| User entered '19 Aug 2020' | (b) (4)<br>Amber Vasquez (b) (4)<br>(b) (4) | 19 Aug 2020 19:23:15 |

US3222220

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:05:20

[Was study treatment given?](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 04 Apr 2021 18:17:07 |
| User signature succeeded. | Bruce Rankin (b) (4)     | 19 Feb 2021 22:18:05 |
| User entered 'Yes (Y)'    | Jennifer Dittman (b) (4) | 19 Aug 2020 17:32:54 |

US3222220

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:05:20

If No, reason not given

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 04 Apr 2021 18:17:07 |
| User signature succeeded. | Bruce Rankin (b) (4)     | 19 Feb 2021 22:18:05 |
| User entered empty.       | Jennifer Dittman (b) (4) | 19 Aug 2020 17:32:54 |

US3222220

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:05:20

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)         | 04 Apr 2021 18:17:07 |
| User signature succeeded. | Bruce Rankin (b) (4)     | 19 Feb 2021 22:18:05 |
| User entered empty.       | Jennifer Dittman (b) (4) | 19 Aug 2020 17:32:54 |

US3222220

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:05:20

[What was the study treatment?](#)

| Audit                               | User             | Time (GMT)           |
|-------------------------------------|------------------|----------------------|
| Data hard locked.                   | (b) (4), (b) (6) | 04 Apr 2021 18:17:07 |
| User entered 'MRNA-1273 OR PLACEBO' | System           | 19 Aug 2020 17:32:54 |



US3222220

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:05:20

What was the treatment date? (dd MMM yyyy)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)         | 04 Apr 2021 18:17:07 |
| User signature succeeded.  | Bruce Rankin (b) (4)     | 19 Feb 2021 22:18:05 |
| User entered '19 Aug 2020' | Jennifer Dittman (b) (4) | 19 Aug 2020 17:32:54 |

US3222220

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:05:20

[What was the treatment time? \(00:00-23:59\)](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 04 Apr 2021 18:17:07 |
| User signature succeeded. | Bruce Rankin (b) (4)     | 19 Feb 2021 22:18:05 |
| User entered '12:51'      | Jennifer Dittman (b) (4) | 19 Aug 2020 17:32:54 |

US3222220

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:05:20

[Treatment Date and Time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Apr 2021 18:17:07 |
| User entered '19 Aug 2020 12:51' | System           | 19 Aug 2020 17:32:54 |

US3222220

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:05:20

[Which arm was used to give treatment?](#)

| Audit                                | User                     | Time (GMT)           |
|--------------------------------------|--------------------------|----------------------|
| Data hard locked.                    | (b) (4), (b) (6)         | 04 Apr 2021 18:17:07 |
| User signature succeeded.            | Bruce Rankin (b) (4)     | 19 Feb 2021 22:18:05 |
| User entered 'Right Arm (RIGHT ARM)' | Jennifer Dittman (b) (4) | 19 Aug 2020 17:32:54 |

US3222220

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:05:20

[What was the frequency of the study treatment dosing?](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Apr 2021 18:17:07 |
| User entered 'ONCE' | System           | 19 Aug 2020 17:32:54 |

US3222220

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:05:20

What was the route of administration for the study treatment?

| Audit                        | User             | Time (GMT)           |
|------------------------------|------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6) | 04 Apr 2021 18:17:07 |
| User entered 'INTRAMUSCULAR' | System           | 19 Aug 2020 17:32:54 |

US3222220

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:20

[Was the sample collected?](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 04 Apr 2021 18:17:07 |
| User signature succeeded. | Bruce Rankin (b) (4)             | 19 Feb 2021 22:18:05 |
| User entered 'Yes (Y)'    | (b) (4)<br>Amber Vasquez (b) (4) | 19 Aug 2020 19:23:59 |

US3222220

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:20

Collection date (*dd MMM yyyy*)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                 | 04 Apr 2021 18:17:07 |
| User signature succeeded.  | Bruce Rankin (b) (4)             | 19 Feb 2021 22:18:05 |
| User entered '19 Aug 2020' | (b) (4)<br>Amber Vasquez (b) (4) | 19 Aug 2020 19:23:59 |



US3222220

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:20

Collection time (00:00-23:59)

| Audit                     | User  | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                            | 04 Apr 2021 18:17:07 |
| User signature succeeded. | Bruce Rankin (b) (4)                        | 19 Feb 2021 22:18:05 |
| User entered '12:45'      | (b) (4)<br>Amber Vasquez (b) (4)<br>(b) (4) | 19 Aug 2020 19:23:59 |

US3222220

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:20

Collection date and time (derived)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Apr 2021 18:17:07 |
| User entered '19 Aug 2020 12:45' | System           | 19 Aug 2020 19:23:59 |

US3222220

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:05:20

Collection date (*dd MMM yyyy*)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                 | 04 Apr 2021 18:17:07 |
| User signature succeeded.  | Bruce Rankin (b) (4)             | 19 Feb 2021 22:18:05 |
| User entered '19 Aug 2020' | (b) (4)<br>Amber Vasquez (b) (4) | 19 Aug 2020 19:24:20 |

US3222220

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:05:20

[Lab Test](#)

| Audit  | User                             | Time (GMT)           |
|--|----------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                 | 04 Apr 2021 18:17:07 |
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | Amber Vasquez (b) (4)<br>(b) (4) | 19 Aug 2020 19:24:20 |

US3222220

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:05:20

[Was the sample collected?](#)

| Audit                     | User  | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                            | 04 Apr 2021 18:17:07 |
| User signature succeeded. | Bruce Rankin (b) (4)                        | 19 Feb 2021 22:18:05 |
| User entered 'Yes (Y)'    | (b) (4)<br>Amber Vasquez (b) (4)<br>(b) (4) | 19 Aug 2020 19:24:20 |

US3222220

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:05:20

Collection time (00:00 - 23:59)

| Audit                     | User  | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                            | 04 Apr 2021 18:17:07 |
| User signature succeeded. | Bruce Rankin (b) (4)                        | 19 Feb 2021 22:18:05 |
| User entered '12:46'      | (b) (4)<br>Amber Vasquez (b) (4)<br>(b) (4) | 19 Aug 2020 19:24:20 |

US3222220

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:05:20

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

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Apr 2021 18:17:07 |
| User entered '19 Aug 2020 12:46' | System           | 19 Aug 2020 19:24:20 |

US3222220

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:05:20

[Lab Test](#)

| Audit  | User                             | Time (GMT)           |
|--|----------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                 | 04 Apr 2021 18:17:07 |
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | Amber Vasquez (b) (4)<br>(b) (4) | 19 Aug 2020 19:24:20 |



US3222220

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:05:20

[Was the sample collected?](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 04 Apr 2021 18:17:07 |
| User signature succeeded. | Bruce Rankin (b) (4)             | 19 Feb 2021 22:18:05 |
| User entered 'No (N)'     | (b) (4)<br>Amber Vasquez (b) (4) | 19 Aug 2020 19:24:20 |

US3222220

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:05:20

Collection time (00:00 - 23:59)

| Audit                     | User  | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                            | 04 Apr 2021 18:17:07 |
| User signature succeeded. | Bruce Rankin (b) (4)                        | 19 Feb 2021 22:18:05 |
| User entered empty.       | (b) (4)<br>Amber Vasquez (b) (4)<br>(b) (4) | 19 Aug 2020 19:24:20 |

US3222220

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:05:20

Collection date and time (derived)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Apr 2021 18:17:07 |
| User entered empty. | System           | 19 Aug 2020 19:24:20 |

US3222220

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:05:20

[Is the participant continuing to the next visit?](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 04 Apr 2021 18:17:07 |
| User signature succeeded. | Bruce Rankin (b) (4)             | 19 Feb 2021 22:18:05 |
| User entered 'Yes (Y)'    | (b) (4)<br>Amber Vasquez (b) (4) | 19 Aug 2020 19:24:30 |

US3222220

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:05:20

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 18:17:07 |
| User entered '1'  | System           | 19 Aug 2020 19:24:30 |

US3222220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:05:20

**TIMEPOINT**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| Data entry locked.   | System           | 19 Aug 2020 17:32:54 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System           | 19 Aug 2020 17:32:54 |

US3222220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:05:20

Was **TEMPERATURE** taken?

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
|                   |                  |                      |

US3222220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:05:20

Please record your **TEMPERATURE** in °F

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
|                   |                  |                      |



US3222220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:05:20

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

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
|                   |                  |                      |

US3222220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:05:20

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

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
|                   |                  |                      |

US3222220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:05:20

To **PREVENT** pain or fever from occurring

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
|                   |                  |                      |

US3222220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:05:20

[PC Time Stamp](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
|                   |                  |                      |

US3222220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:05:20

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| User entered '19 Aug 2020 13:11' | System           | 19 Aug 2020 17:32:54 |

US3222220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:05:20

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| User entered '19 Aug 2020 15:41' | System           | 19 Aug 2020 17:32:54 |

US3222220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:05:20

**TIMEPOINT**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| Data entry locked.                                | System           | 19 Aug 2020 17:32:54 |
| User entered 'Day 1, after vaccination (at home)' | System           | 19 Aug 2020 17:32:54 |

US3222220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:05:20

Was **TEMPERATURE** taken?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b170983e9afc191a)', Time: '2020-08-19T18:46:38', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '21aad466-3c4b-4c32-b80b-710cb3bdf78' | System           | 19 Aug 2020 22:47:38 |
| User entered 'Yes (Y)'  | System           | 19 Aug 2020 22:47:38 |



US3222220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:05:20

Please record your **TEMPERATURE** in °F

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b170983e9afc191a)', Time: '2020-08-19T18:47:12', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '21aad466-3c4b-4c32-b80b-710cb3bdf78' | System           | 19 Aug 2020 22:47:38 |
| User entered '99.1'   | System           | 19 Aug 2020 22:47:38 |

US3222220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:05:20

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

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b170983e9afc191a)', Time: '2020-08-19T18:47:25', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '21aad466-3c4b-4c32-b80b-710cb3bdf78' | System           | 19 Aug 2020 22:47:38 |
| User entered 'No (N)'   | System           | 19 Aug 2020 22:47:38 |

US3222220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:05:20

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b170983e9afc191a)', Time: '2020-08-19T18:47:36', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '21aad466-3c4b-4c32-b80b-710cb3bdf78' | System           | 19 Aug 2020 22:47:38 |
| User entered '19 Aug 2020 18:47'  | System           | 19 Aug 2020 22:47:38 |

US3222220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:05:20

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| User entered '19 Aug 2020 16:36' | System           | 19 Aug 2020 17:32:54 |

US3222220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:05:20

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| User entered '20 Aug 2020 11:59' | System           | 19 Aug 2020 17:32:54 |

US3222220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:05:20

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| Data entry locked.   | System           | 19 Aug 2020 17:32:54 |
| User entered 'Day 2' | System           | 19 Aug 2020 17:32:54 |

US3222220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:05:20

Was **TEMPERATURE** taken?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b170983e9afc191a)', Time: '2020-08-20T21:40:43', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: 'cf2c04a4-c8e9-4862-895c-9f100643c05a' | System           | 21 Aug 2020 01:41:41 |
| User entered 'Yes (Y)'   | System           | 21 Aug 2020 01:41:41 |

US3222220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:05:20

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b170983e9afc191a)', Time: '2020-08-20T21:41:19', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: 'cf2c04a4-c8e9-4862-895c-9f100643c05a' | System           | 21 Aug 2020 01:41:41 |
| User entered '98.5'  | System           | 21 Aug 2020 01:41:41 |



US3222220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:05:20

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b170983e9afc191a)', Time: '2020-08-20T21:41:27', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: 'cf2c04a4-c8e9-4862-895c-9f100643c05a' | System           | 21 Aug 2020 01:41:41 |
| User entered 'No (N)'  | System           | 21 Aug 2020 01:41:41 |

US3222220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:05:20

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b170983e9afc191a)', Time: '2020-08-20T21:41:37', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: 'cf2c04a4-c8e9-4862-895c-9f100643c05a' | System           | 21 Aug 2020 01:41:41 |
| User entered '20 Aug 2020 21:41'   | System           | 21 Aug 2020 01:41:41 |

US3222220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:05:20

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| User entered '20 Aug 2020 12:00' | System           | 19 Aug 2020 17:32:54 |

US3222220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:05:20

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| User entered '21 Aug 2020 11:59' | System           | 19 Aug 2020 17:32:54 |

US3222220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:05:20

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| Data entry locked.   | System           | 19 Aug 2020 17:32:54 |
| User entered 'Day 3' | System           | 19 Aug 2020 17:32:54 |

US3222220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:05:20

Was **TEMPERATURE** taken?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b170983e9afc191a)', Time: '2020-08-22T07:38:25', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: 'f0336612-e0f3-4df9-89d2-8d8d42c4e8da' | System           | 22 Aug 2020 11:38:52 |
| User entered 'Yes (Y)'   | System           | 22 Aug 2020 11:38:52 |

US3222220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:05:20

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b170983e9afc191a)', Time: '2020-08-22T07:38:34', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: 'f0336612-e0f3-4df9-89d2-8d8d42c4e8da' | System           | 22 Aug 2020 11:38:52 |
| User entered '99.2'  | System           | 22 Aug 2020 11:38:52 |

US3222220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:05:20

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b170983e9afc191a)', Time: '2020-08-22T07:38:40', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: 'f0336612-e0f3-4df9-89d2-8d8d42c4e8da' | System           | 22 Aug 2020 11:38:52 |
| User entered 'No (N)'  | System           | 22 Aug 2020 11:38:52 |



US3222220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:05:20

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b170983e9afc191a)', Time: '2020-08-22T07:38:49', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: 'f0336612-e0f3-4df9-89d2-8d8d42c4e8da' | System           | 22 Aug 2020 11:38:52 |
| User entered '22 Aug 2020 07:38'   | System           | 22 Aug 2020 11:38:52 |

US3222220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:05:20

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| User entered '21 Aug 2020 12:00' | System           | 19 Aug 2020 17:32:54 |

US3222220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:05:20

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| User entered '22 Aug 2020 11:59' | System           | 19 Aug 2020 17:32:54 |

US3222220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:05:20

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| Data entry locked.   | System           | 19 Aug 2020 17:32:54 |
| User entered 'Day 4' | System           | 19 Aug 2020 17:32:54 |

US3222220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:05:20

Was **TEMPERATURE** taken?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b170983e9afc191a)', Time: '2020-08-22T20:55:04', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '4fa2318a-c946-482b-8e9b-39aaefe87c6b' | System           | 23 Aug 2020 00:56:00 |
| User entered 'Yes (Y)'   | System           | 23 Aug 2020 00:56:00 |

US3222220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:05:20

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b170983e9afc191a)', Time: '2020-08-22T20:55:41', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '4fa2318a-c946-482b-8e9b-39aaefe87c6b' | System           | 23 Aug 2020 00:56:00 |
| User entered '98.7'  | System           | 23 Aug 2020 00:56:00 |

US3222220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:05:20

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b170983e9afc191a)', Time: '2020-08-22T20:55:47', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '4fa2318a-c946-482b-8e9b-39aaefe87c6b' | System           | 23 Aug 2020 00:56:00 |
| User entered 'No (N)'  | System           | 23 Aug 2020 00:56:00 |

US3222220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:05:20

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b170983e9afc191a)', Time: '2020-08-22T20:55:57', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '4fa2318a-c946-482b-8e9b-39aaefe87c6b' | System           | 23 Aug 2020 00:56:00 |
| User entered '22 Aug 2020 20:55'   | System           | 23 Aug 2020 00:56:00 |



US3222220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:05:20

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| User entered '22 Aug 2020 12:00' | System           | 19 Aug 2020 17:32:54 |

US3222220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:05:20

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| User entered '23 Aug 2020 11:59' | System           | 19 Aug 2020 17:32:54 |

US3222220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:05:20

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| Data entry locked.   | System           | 19 Aug 2020 17:32:54 |
| User entered 'Day 5' | System           | 19 Aug 2020 17:32:54 |

US3222220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:05:20

Was **TEMPERATURE** taken?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b170983e9afc191a)', Time: '2020-08-24T00:45:29', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '79da886b-0e6a-42f7-902e-0a0cf40d028e' | System           | 24 Aug 2020 04:46:02 |
| User entered 'Yes (Y)'   | System           | 24 Aug 2020 04:46:02 |

US3222220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:05:20

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b170983e9afc191a)', Time: '2020-08-24T00:45:42', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '79da886b-0e6a-42f7-902e-0a0cf40d028e' | System           | 24 Aug 2020 04:46:02 |
| User entered '98.7'  | System           | 24 Aug 2020 04:46:02 |

US3222220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:05:20

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b170983e9afc191a)', Time: '2020-08-24T00:45:46', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '79da886b-0e6a-42f7-902e-0a0cf40d028e' | System           | 24 Aug 2020 04:46:02 |
| User entered 'No (N)'  | System           | 24 Aug 2020 04:46:02 |

US3222220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:05:20

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b170983e9afc191a)', Time: '2020-08-24T00:45:59', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '79da886b-0e6a-42f7-902e-0a0cf40d028e' | System           | 24 Aug 2020 04:46:02 |
| User entered '24 Aug 2020 00:45'   | System           | 24 Aug 2020 04:46:02 |

US3222220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:05:20

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| User entered '23 Aug 2020 12:00' | System           | 19 Aug 2020 17:32:54 |



US3222220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:05:20

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| User entered '24 Aug 2020 11:59' | System           | 19 Aug 2020 17:32:54 |

US3222220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:05:20

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| Data entry locked.   | System           | 19 Aug 2020 17:32:54 |
| User entered 'Day 6' | System           | 19 Aug 2020 17:32:54 |

US3222220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:05:20

Was **TEMPERATURE** taken?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b170983e9afc191a)', Time: '2020-08-24T18:43:55', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '9c13f0e3-b866-4cde-85f5-ce9a5b87d7c1' | System           | 24 Aug 2020 22:44:24 |
| User entered 'Yes (Y)'   | System           | 24 Aug 2020 22:44:24 |

US3222220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:05:20

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b170983e9afc191a)', Time: '2020-08-24T18:44:10', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '9c13f0e3-b866-4cde-85f5-ce9a5b87d7c1' | System           | 24 Aug 2020 22:44:24 |
| User entered '98.9'  | System           | 24 Aug 2020 22:44:24 |

US3222220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:05:20

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b170983e9afc191a)', Time: '2020-08-24T18:44:15', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '9c13f0e3-b866-4cde-85f5-ce9a5b87d7c1' | System           | 24 Aug 2020 22:44:24 |
| User entered 'No (N)'  | System           | 24 Aug 2020 22:44:24 |

US3222220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:05:20

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b170983e9afc191a)', Time: '2020-08-24T18:44:20', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '9c13f0e3-b866-4cde-85f5-ce9a5b87d7c1' | System           | 24 Aug 2020 22:44:24 |
| User entered '24 Aug 2020 18:44'   | System           | 24 Aug 2020 22:44:24 |

US3222220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:05:20

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| User entered '24 Aug 2020 12:00' | System           | 19 Aug 2020 17:32:54 |

US3222220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:05:20

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| User entered '25 Aug 2020 11:59' | System           | 19 Aug 2020 17:32:54 |



US3222220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:05:20

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| Data entry locked.   | System           | 19 Aug 2020 17:32:54 |
| User entered 'Day 7' | System           | 19 Aug 2020 17:32:54 |

US3222220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:05:20

Was **TEMPERATURE** taken?

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
|                   |                  |                      |

US3222220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:05:20

Please record your **TEMPERATURE** in °F

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
|                   |                  |                      |

US3222220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:05:20

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

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
|                   |                  |                      |

US3222220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:05:20

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

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
|                   |                  |                      |

US3222220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:05:20

To **PREVENT** pain or fever from occurring

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
|                   |                  |                      |

US3222220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:05:20

[PC Time Stamp](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
|                   |                  |                      |

US3222220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:05:20

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| User entered '25 Aug 2020 12:00' | System           | 19 Aug 2020 17:32:54 |



US3222220

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:05:20

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| User entered '26 Aug 2020 11:59' | System           | 19 Aug 2020 17:32:54 |

US3222220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:05:20

**TIMEPOINT**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| Data entry locked.   | System           | 19 Aug 2020 17:32:54 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System           | 19 Aug 2020 17:32:54 |

US3222220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:05:20

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

Please select one response below

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
|                   |                  |                      |

US3222220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:05:20

Is there any REDNESS AT INJECTION SITE?

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
|                   |                  |                      |

US3222220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:05:20

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) | 05 Mar 2021 01:44:16 |

US3222220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:05:20

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

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
|                   |                  |                      |

US3222220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:05:20

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) | 05 Mar 2021 01:44:16 |

US3222220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:05:20

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

Please select one response below

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
|                   |                  |                      |



US3222220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:05:20

[PC Time Stamp](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
|                   |                  |                      |

US3222220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:05:20

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| User entered '19 Aug 2020 13:11' | System           | 19 Aug 2020 17:32:54 |

US3222220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:05:20

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| User entered '19 Aug 2020 15:41' | System           | 19 Aug 2020 17:32:54 |

US3222220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:05:20

**TIMEPOINT**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| Data entry locked.                                | System           | 19 Aug 2020 17:32:54 |
| User entered 'Day 1, after vaccination (at home)' | System           | 19 Aug 2020 17:32:54 |

US3222220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:05:20

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b170983e9afc191a)', Time: '2020-08-19T18:47:56', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: 'd77187a2-5316-4b86-8023-e2fa2b4c86cb' | System           | 19 Aug 2020 22:48:22 |
| User entered 'None (1)'  | System           | 19 Aug 2020 22:48:22 |

US3222220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:05:20

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b170983e9afc191a)', Time: '2020-08-19T18:48:00', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: 'd77187a2-5316-4b86-8023-e2fa2b4c86cb' | System           | 19 Aug 2020 22:48:22 |
| User entered 'No (N)'  | System           | 19 Aug 2020 22:48:22 |

US3222220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:05:20

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b170983e9afc191a)', Time: '2020-08-19T18:48:05', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: 'd77187a2-5316-4b86-8023-e2fa2b4c86cb' | System           | 19 Aug 2020 22:48:22 |
| User entered 'No (N)'  | System           | 19 Aug 2020 22:48:22 |

US3222220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:05:20

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b170983e9afc191a)', Time: '2020-08-19T18:48:11', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: 'd77187a2-5316-4b86-8023-e2fa2b4c86cb' | System           | 19 Aug 2020 22:48:22 |
| User entered 'None (1)'  | System           | 19 Aug 2020 22:48:22 |



US3222220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:05:20

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b170983e9afc191a)', Time: '2020-08-19T18:48:20', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: 'd77187a2-5316-4b86-8023-e2fa2b4c86cb' | System           | 19 Aug 2020 22:48:22 |
| User entered '19 Aug 2020 18:48'   | System           | 19 Aug 2020 22:48:22 |

US3222220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:05:20

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| User entered '19 Aug 2020 16:36' | System           | 19 Aug 2020 17:32:54 |

US3222220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:05:20

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| User entered '20 Aug 2020 11:59' | System           | 19 Aug 2020 17:32:54 |

US3222220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:05:20

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| Data entry locked.   | System           | 19 Aug 2020 17:32:54 |
| User entered 'Day 2' | System           | 19 Aug 2020 17:32:54 |

US3222220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:05:20

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b170983e9afc191a)', Time: '2020-08-20T21:42:17', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: 'c4392891-5e87-4231-8f82-3324cd745d7e' | System           | 21 Aug 2020 01:42:28 |
| User entered 'None (1)'  | System           | 21 Aug 2020 01:42:28 |

US3222220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:05:20

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b170983e9afc191a)', Time: '2020-08-20T21:41:57', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: 'c4392891-5e87-4231-8f82-3324cd745d7e' | System           | 21 Aug 2020 01:42:28 |
| User entered 'No (N)'  | System           | 21 Aug 2020 01:42:28 |

US3222220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:05:20

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b170983e9afc191a)', Time: '2020-08-20T21:42:01', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: 'c4392891-5e87-4231-8f82-3324cd745d7e' | System           | 21 Aug 2020 01:42:28 |
| User entered 'No (N)'  | System           | 21 Aug 2020 01:42:28 |

US3222220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:05:20

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b170983e9afc191a)', Time: '2020-08-20T21:42:08', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: 'c4392891-5e87-4231-8f82-3324cd745d7e' | System           | 21 Aug 2020 01:42:28 |
| User entered 'None (1)'  | System           | 21 Aug 2020 01:42:28 |



US3222220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:05:20

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b170983e9afc191a)', Time: '2020-08-20T21:42:22', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: 'c4392891-5e87-4231-8f82-3324cd745d7e' | System           | 21 Aug 2020 01:42:28 |
| User entered '20 Aug 2020 21:42'   | System           | 21 Aug 2020 01:42:28 |

US3222220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:05:20

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| User entered '20 Aug 2020 12:00' | System           | 19 Aug 2020 17:32:54 |

US3222220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:05:20

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| User entered '21 Aug 2020 11:59' | System           | 19 Aug 2020 17:32:54 |

US3222220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:05:20

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| Data entry locked.   | System           | 19 Aug 2020 17:32:54 |
| User entered 'Day 3' | System           | 19 Aug 2020 17:32:54 |

US3222220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:05:20

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b170983e9afc191a)', Time: '2020-08-22T07:40:37', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: 'fa9b5c50-a658-4f04-9778-9272e2c13c23' | System           | 22 Aug 2020 11:41:03 |
| User entered 'None (1)'  | System           | 22 Aug 2020 11:41:03 |

US3222220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:05:20

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b170983e9afc191a)', Time: '2020-08-22T07:40:41', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: 'fa9b5c50-a658-4f04-9778-9272e2c13c23' | System           | 22 Aug 2020 11:41:03 |
| User entered 'No (N)'  | System           | 22 Aug 2020 11:41:03 |

US3222220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:05:20

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b170983e9afc191a)', Time: '2020-08-22T07:40:45', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: 'fa9b5c50-a658-4f04-9778-9272e2c13c23' | System           | 22 Aug 2020 11:41:03 |
| User entered 'No (N)'  | System           | 22 Aug 2020 11:41:03 |

US3222220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:05:20

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b170983e9afc191a)', Time: '2020-08-22T07:40:51', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: 'fa9b5c50-a658-4f04-9778-9272e2c13c23' | System           | 22 Aug 2020 11:41:03 |
| User entered 'None (1)'  | System           | 22 Aug 2020 11:41:03 |



US3222220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:05:20

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b170983e9afc191a)', Time: '2020-08-22T07:41:00', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: 'fa9b5c50-a658-4f04-9778-9272e2c13c23' | System           | 22 Aug 2020 11:41:03 |
| User entered '22 Aug 2020 07:41'   | System           | 22 Aug 2020 11:41:03 |

US3222220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:05:20

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| User entered '21 Aug 2020 12:00' | System           | 19 Aug 2020 17:32:54 |

US3222220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:05:20

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| User entered '22 Aug 2020 11:59' | System           | 19 Aug 2020 17:32:54 |

US3222220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:05:20

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| Data entry locked.   | System           | 19 Aug 2020 17:32:54 |
| User entered 'Day 4' | System           | 19 Aug 2020 17:32:54 |

US3222220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:05:20

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b170983e9afc191a)', Time: '2020-08-22T20:56:10', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '5253ca5a-bbb1-4d72-819d-bb33372a7423' | System           | 23 Aug 2020 00:56:41 |
| User entered 'None (1)'  | System           | 23 Aug 2020 00:56:41 |

US3222220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:05:20

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b170983e9afc191a)', Time: '2020-08-22T20:56:13', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '5253ca5a-bbb1-4d72-819d-bb33372a7423' | System           | 23 Aug 2020 00:56:41 |
| User entered 'No (N)'  | System           | 23 Aug 2020 00:56:41 |

US3222220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:05:20

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b170983e9afc191a)', Time: '2020-08-22T20:56:17', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '5253ca5a-bbb1-4d72-819d-bb33372a7423' | System           | 23 Aug 2020 00:56:41 |
| User entered 'No (N)'  | System           | 23 Aug 2020 00:56:41 |

US3222220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:05:20

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b170983e9afc191a)', Time: '2020-08-22T20:56:31', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '5253ca5a-bbb1-4d72-819d-bb33372a7423' | System           | 23 Aug 2020 00:56:41 |
| User entered 'Does not interfere with activity (2)'  | System           | 23 Aug 2020 00:56:41 |



US3222220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:05:20

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b170983e9afc191a)', Time: '2020-08-22T20:56:37', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '5253ca5a-bbb1-4d72-819d-bb33372a7423' | System           | 23 Aug 2020 00:56:41 |
| User entered '22 Aug 2020 20:56'   | System           | 23 Aug 2020 00:56:41 |

US3222220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:05:20

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| User entered '22 Aug 2020 12:00' | System           | 19 Aug 2020 17:32:54 |

US3222220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:05:20

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| User entered '23 Aug 2020 11:59' | System           | 19 Aug 2020 17:32:54 |

US3222220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:05:20

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| Data entry locked.   | System           | 19 Aug 2020 17:32:54 |
| User entered 'Day 5' | System           | 19 Aug 2020 17:32:54 |

US3222220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:05:20

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b170983e9afc191a)', Time: '2020-08-24T00:46:06', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '63bf19bd-bac9-4148-a3a4-c36b01586a4d' | System           | 24 Aug 2020 04:46:36 |
| User entered 'None (1)'  | System           | 24 Aug 2020 04:46:36 |

US3222220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:05:20

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b170983e9afc191a)', Time: '2020-08-24T00:46:10', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '63bf19bd-bac9-4148-a3a4-c36b01586a4d' | System           | 24 Aug 2020 04:46:36 |
| User entered 'No (N)'  | System           | 24 Aug 2020 04:46:36 |

US3222220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:05:20

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b170983e9afc191a)', Time: '2020-08-24T00:46:13', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '63bf19bd-bac9-4148-a3a4-c36b01586a4d' | System           | 24 Aug 2020 04:46:36 |
| User entered 'No (N)'  | System           | 24 Aug 2020 04:46:36 |

US3222220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:05:20

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b170983e9afc191a)', Time: '2020-08-24T00:46:25', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '63bf19bd-bac9-4148-a3a4-c36b01586a4d' | System           | 24 Aug 2020 04:46:36 |
| User entered 'None (1)'  | System           | 24 Aug 2020 04:46:36 |



US3222220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:05:20

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b170983e9afc191a)', Time: '2020-08-24T00:46:31', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '63bf19bd-bac9-4148-a3a4-c36b01586a4d' | System           | 24 Aug 2020 04:46:36 |
| User entered '24 Aug 2020 00:46'   | System           | 24 Aug 2020 04:46:36 |

US3222220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:05:20

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| User entered '23 Aug 2020 12:00' | System           | 19 Aug 2020 17:32:54 |

US3222220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:05:20

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| User entered '24 Aug 2020 11:59' | System           | 19 Aug 2020 17:32:54 |

US3222220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:05:20

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| Data entry locked.   | System           | 19 Aug 2020 17:32:54 |
| User entered 'Day 6' | System           | 19 Aug 2020 17:32:54 |

US3222220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:05:20

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b170983e9afc191a)', Time: '2020-08-24T18:44:26', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '68077740-0490-4aea-9482-47c5c8933b3e' | System           | 24 Aug 2020 22:44:44 |
| User entered 'None (1)'  | System           | 24 Aug 2020 22:44:44 |

US3222220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:05:20

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b170983e9afc191a)', Time: '2020-08-24T18:44:30', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '68077740-0490-4aea-9482-47c5c8933b3e' | System           | 24 Aug 2020 22:44:44 |
| User entered 'No (N)'  | System           | 24 Aug 2020 22:44:44 |

US3222220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:05:20

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b170983e9afc191a)', Time: '2020-08-24T18:44:32', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '68077740-0490-4aea-9482-47c5c8933b3e' | System           | 24 Aug 2020 22:44:44 |
| User entered 'No (N)'  | System           | 24 Aug 2020 22:44:44 |

US3222220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:05:20

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b170983e9afc191a)', Time: '2020-08-24T18:44:38', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '68077740-0490-4aea-9482-47c5c8933b3e' | System           | 24 Aug 2020 22:44:44 |
| User entered 'None (1)'  | System           | 24 Aug 2020 22:44:44 |



US3222220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:05:20

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b170983e9afc191a)', Time: '2020-08-24T18:44:41', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '68077740-0490-4aea-9482-47c5c8933b3e' | System           | 24 Aug 2020 22:44:44 |
| User entered '24 Aug 2020 18:44'   | System           | 24 Aug 2020 22:44:44 |

US3222220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:05:20

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| User entered '24 Aug 2020 12:00' | System           | 19 Aug 2020 17:32:54 |

US3222220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:05:20

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| User entered '25 Aug 2020 11:59' | System           | 19 Aug 2020 17:32:54 |

US3222220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:05:20

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| Data entry locked.   | System           | 19 Aug 2020 17:32:54 |
| User entered 'Day 7' | System           | 19 Aug 2020 17:32:54 |

US3222220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:05:20

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

Please select one response below

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
|                   |                  |                      |

US3222220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:05:20

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

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
|                   |                  |                      |

US3222220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:05:20

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) | 05 Mar 2021 01:44:16 |
|                   |                  |                      |

US3222220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:05:20

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

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
|                   |                  |                      |



US3222220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:05:20

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) | 05 Mar 2021 01:44:16 |

US3222220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:05:20

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

Please select one response below

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
|                   |                  |                      |

US3222220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:05:20

[PC Time Stamp](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
|                   |                  |                      |

US3222220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:05:20

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| User entered '25 Aug 2020 12:00' | System           | 19 Aug 2020 17:32:54 |

US3222220

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:05:20

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| User entered '26 Aug 2020 11:59' | System           | 19 Aug 2020 17:32:54 |

US3222220

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:05:20

**TIMEPOINT**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| Data entry locked.   | System           | 19 Aug 2020 17:32:54 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System           | 19 Aug 2020 17:32:54 |

US3222220

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:05:20

**HEADACHE**

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
|                   |                  |                      |

US3222220

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:05:20

**FATIGUE**

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
|                   |                  |                      |



US3222220

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:05:20

**MUSCLE ACHES ALL OVER BODY**

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
|                   |                  |                      |

US3222220

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:05:20

**JOINT ACHES IN SEVERAL JOINTS**

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
|                   |                  |                      |

US3222220

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:05:20

**NAUSEA/VOMITING**

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
|                   |                  |                      |

US3222220

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:05:20

**CHILLS**

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
|                   |                  |                      |

US3222220

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:05:20

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) | 05 Mar 2021 01:44:16 |
|                   |                  |                      |

US3222220

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:05:20

[PC Time stamp](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
|                   |                  |                      |

US3222220

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:05:20

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| User entered '19 Aug 2020 13:11' | System           | 19 Aug 2020 17:32:54 |

US3222220

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:05:20

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| User entered '19 Aug 2020 15:41' | System           | 19 Aug 2020 17:32:54 |



US3222220

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:05:20

**TIMEPOINT**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| Data entry locked.                                | System           | 19 Aug 2020 17:32:54 |
| User entered 'Day 1, after vaccination (at home)' | System           | 19 Aug 2020 17:32:54 |

US3222220

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:05:20

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b170983e9afc191a)', Time: '2020-08-19T18:48:27', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '9239f874-f8fd-4213-8f92-6d006412cdc9' | System           | 19 Aug 2020 22:49:07 |
| User entered 'None (0)'  | System           | 19 Aug 2020 22:49:07 |

US3222220

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:05:20

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b170983e9afc191a)', Time: '2020-08-19T18:48:33', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '9239f874-f8fd-4213-8f92-6d006412cdc9' | System           | 19 Aug 2020 22:49:07 |
| User entered 'None (0)'  | System           | 19 Aug 2020 22:49:07 |

US3222220

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:05:20

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b170983e9afc191a)', Time: '2020-08-19T18:48:37', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '9239f874-f8fd-4213-8f92-6d006412cdc9' | System           | 19 Aug 2020 22:49:07 |
| User entered 'None (0)'  | System           | 19 Aug 2020 22:49:07 |

US3222220

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:05:20

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b170983e9afc191a)', Time: '2020-08-19T18:48:41', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '9239f874-f8fd-4213-8f92-6d006412cdc9' | System           | 19 Aug 2020 22:49:07 |
| User entered 'None (0)'  | System           | 19 Aug 2020 22:49:07 |

US3222220

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:05:20

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b170983e9afc191a)', Time: '2020-08-19T18:48:45', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '9239f874-f8fd-4213-8f92-6d006412cdc9' | System           | 19 Aug 2020 22:49:07 |
| User entered 'None (0)'  | System           | 19 Aug 2020 22:49:07 |

US3222220

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:05:20

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b170983e9afc191a)', Time: '2020-08-19T18:48:48', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '9239f874-f8fd-4213-8f92-6d006412cdc9' | System           | 19 Aug 2020 22:49:07 |
| User entered 'None (0)'  | System           | 19 Aug 2020 22:49:07 |

US3222220

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:05:20

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) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b170983e9afc191a)', Time: '2020-08-19T18:48:52', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '9239f874-f8fd-4213-8f92-6d006412cdc9' | System           | 19 Aug 2020 22:49:07 |
| User entered 'No (N)'  | System           | 19 Aug 2020 22:49:07 |



US3222220

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:05:20

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b170983e9afc191a)', Time: '2020-08-19T18:49:00', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '9239f874-f8fd-4213-8f92-6d006412cdc9' | System           | 19 Aug 2020 22:49:07 |
| User entered '19 Aug 2020 18:49'   | System           | 19 Aug 2020 22:49:07 |

US3222220

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:05:20

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| User entered '19 Aug 2020 16:36' | System           | 19 Aug 2020 17:32:54 |

US3222220

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:05:20

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| User entered '20 Aug 2020 11:59' | System           | 19 Aug 2020 17:32:54 |

US3222220

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:05:20

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| Data entry locked.   | System           | 19 Aug 2020 17:32:54 |
| User entered 'Day 2' | System           | 19 Aug 2020 17:32:54 |

US3222220

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:05:20

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b170983e9afc191a)', Time: '2020-08-20T21:42:57', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '29a34b88-dd4e-4c5b-aff9-293b8171811b' | System           | 21 Aug 2020 01:43:02 |
| User entered 'None (0)'  | System           | 21 Aug 2020 01:43:02 |

US3222220

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:05:20

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b170983e9afc191a)', Time: '2020-08-20T21:42:37', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '29a34b88-dd4e-4c5b-aff9-293b8171811b' | System           | 21 Aug 2020 01:43:02 |
| User entered 'None (0)'  | System           | 21 Aug 2020 01:43:02 |

US3222220

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:05:20

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b170983e9afc191a)', Time: '2020-08-20T21:42:40', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '29a34b88-dd4e-4c5b-aff9-293b8171811b' | System           | 21 Aug 2020 01:43:02 |
| User entered 'None (0)'  | System           | 21 Aug 2020 01:43:02 |

US3222220

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:05:20

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b170983e9afc191a)', Time: '2020-08-20T21:42:42', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '29a34b88-dd4e-4c5b-aff9-293b8171811b' | System           | 21 Aug 2020 01:43:02 |
| User entered 'None (0)'  | System           | 21 Aug 2020 01:43:02 |



US3222220

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:05:20

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b170983e9afc191a)', Time: '2020-08-20T21:42:44', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '29a34b88-dd4e-4c5b-aff9-293b8171811b' | System           | 21 Aug 2020 01:43:02 |
| User entered 'None (0)'  | System           | 21 Aug 2020 01:43:02 |

US3222220

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:05:20

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b170983e9afc191a)', Time: '2020-08-20T21:42:46', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '29a34b88-dd4e-4c5b-aff9-293b8171811b' | System           | 21 Aug 2020 01:43:02 |
| User entered 'None (0)'  | System           | 21 Aug 2020 01:43:02 |

US3222220

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:05:20

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) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b170983e9afc191a)', Time: '2020-08-20T21:42:52', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '29a34b88-dd4e-4c5b-aff9-293b8171811b' | System           | 21 Aug 2020 01:43:02 |
| User entered 'No (N)'  | System           | 21 Aug 2020 01:43:02 |

US3222220

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:05:20

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b170983e9afc191a)', Time: '2020-08-20T21:43:00', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '29a34b88-dd4e-4c5b-aff9-293b8171811b' | System           | 21 Aug 2020 01:43:02 |
| User entered '20 Aug 2020 21:43'   | System           | 21 Aug 2020 01:43:02 |

US3222220

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:05:20

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| User entered '20 Aug 2020 12:00' | System           | 19 Aug 2020 17:32:54 |

US3222220

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:05:20

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| User entered '21 Aug 2020 11:59' | System           | 19 Aug 2020 17:32:54 |

US3222220

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:05:20

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| Data entry locked.   | System           | 19 Aug 2020 17:32:54 |
| User entered 'Day 3' | System           | 19 Aug 2020 17:32:54 |

US3222220

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:05:20

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b170983e9afc191a)', Time: '2020-08-22T07:41:21', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '7c08b2d1-8560-4e2e-bac7-05640766bb0c' | System           | 22 Aug 2020 11:41:55 |
| User entered 'None (0)'  | System           | 22 Aug 2020 11:41:55 |



US3222220

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:05:20

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b170983e9afc191a)', Time: '2020-08-22T07:41:25', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '7c08b2d1-8560-4e2e-bac7-05640766bb0c' | System           | 22 Aug 2020 11:41:55 |
| User entered 'None (0)'  | System           | 22 Aug 2020 11:41:55 |

US3222220

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:05:20

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b170983e9afc191a)', Time: '2020-08-22T07:41:29', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '7c08b2d1-8560-4e2e-bac7-05640766bb0c' | System           | 22 Aug 2020 11:41:55 |
| User entered 'None (0)'  | System           | 22 Aug 2020 11:41:55 |

US3222220

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:05:20

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b170983e9afc191a)', Time: '2020-08-22T07:41:35', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '7c08b2d1-8560-4e2e-bac7-05640766bb0c' | System           | 22 Aug 2020 11:41:55 |
| User entered 'None (0)'  | System           | 22 Aug 2020 11:41:55 |

US3222220

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:05:20

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b170983e9afc191a)', Time: '2020-08-22T07:41:39', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '7c08b2d1-8560-4e2e-bac7-05640766bb0c' | System           | 22 Aug 2020 11:41:55 |
| User entered 'None (0)'  | System           | 22 Aug 2020 11:41:55 |

US3222220

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:05:20

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b170983e9afc191a)', Time: '2020-08-22T07:41:42', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '7c08b2d1-8560-4e2e-bac7-05640766bb0c' | System           | 22 Aug 2020 11:41:55 |
| User entered 'None (0)'  | System           | 22 Aug 2020 11:41:55 |

US3222220

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:05:20

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) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b170983e9afc191a)', Time: '2020-08-22T07:41:47', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '7c08b2d1-8560-4e2e-bac7-05640766bb0c' | System           | 22 Aug 2020 11:41:55 |
| User entered 'No (N)'  | System           | 22 Aug 2020 11:41:55 |

US3222220

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:05:20

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b170983e9afc191a)', Time: '2020-08-22T07:41:52', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '7c08b2d1-8560-4e2e-bac7-05640766bb0c' | System           | 22 Aug 2020 11:41:55 |
| User entered '22 Aug 2020 07:41'   | System           | 22 Aug 2020 11:41:55 |

US3222220

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:05:20

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| User entered '21 Aug 2020 12:00' | System           | 19 Aug 2020 17:32:54 |



US3222220

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:05:20

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| User entered '22 Aug 2020 11:59' | System           | 19 Aug 2020 17:32:54 |

US3222220

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:05:20

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| Data entry locked.   | System           | 19 Aug 2020 17:32:54 |
| User entered 'Day 4' | System           | 19 Aug 2020 17:32:54 |

US3222220

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:05:20

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b170983e9afc191a)', Time: '2020-08-22T20:56:44', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '55bacfb9-3e34-4994-b951-9105fff31a3f' | System           | 23 Aug 2020 00:57:27 |
| User entered 'None (0)'  | System           | 23 Aug 2020 00:57:27 |

US3222220

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:05:20

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b170983e9afc191a)', Time: '2020-08-22T20:56:48', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '55bacfb9-3e34-4994-b951-9105fff31a3f' | System           | 23 Aug 2020 00:57:27 |
| User entered 'None (0)'  | System           | 23 Aug 2020 00:57:27 |

US3222220

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:05:20

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b170983e9afc191a)', Time: '2020-08-22T20:56:56', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '55bacfb9-3e34-4994-b951-9105fff31a3f' | System           | 23 Aug 2020 00:57:27 |
| User entered 'None (0)'  | System           | 23 Aug 2020 00:57:27 |

US3222220

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:05:20

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b170983e9afc191a)', Time: '2020-08-22T20:57:03', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '55bacfb9-3e34-4994-b951-9105fff31a3f' | System           | 23 Aug 2020 00:57:27 |
| User entered 'None (0)'  | System           | 23 Aug 2020 00:57:27 |

US3222220

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:05:20

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b170983e9afc191a)', Time: '2020-08-22T20:57:12', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '55bacfb9-3e34-4994-b951-9105fff31a3f' | System           | 23 Aug 2020 00:57:27 |
| User entered 'None (0)'  | System           | 23 Aug 2020 00:57:27 |

US3222220

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:05:20

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b170983e9afc191a)', Time: '2020-08-22T20:57:15', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '55bacfb9-3e34-4994-b951-9105fff31a3f' | System           | 23 Aug 2020 00:57:27 |
| User entered 'None (0)'  | System           | 23 Aug 2020 00:57:27 |



US3222220

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:05:20

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) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b170983e9afc191a)', Time: '2020-08-22T20:57:21', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '55bacfb9-3e34-4994-b951-9105fff31a3f' | System           | 23 Aug 2020 00:57:27 |
| User entered 'No (N)'  | System           | 23 Aug 2020 00:57:27 |

US3222220

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:05:20

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b170983e9afc191a)', Time: '2020-08-22T20:57:24', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '55bacfb9-3e34-4994-b951-9105fff31a3f' | System           | 23 Aug 2020 00:57:27 |
| User entered '22 Aug 2020 20:57'   | System           | 23 Aug 2020 00:57:27 |

US3222220

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:05:20

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| User entered '22 Aug 2020 12:00' | System           | 19 Aug 2020 17:32:54 |

US3222220

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:05:20

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| User entered '23 Aug 2020 11:59' | System           | 19 Aug 2020 17:32:54 |

US3222220

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:05:20

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| Data entry locked.   | System           | 19 Aug 2020 17:32:54 |
| User entered 'Day 5' | System           | 19 Aug 2020 17:32:54 |

US3222220

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:05:20

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b170983e9afc191a)', Time: '2020-08-24T00:46:40', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '8ca668e6-0148-4024-bfda-e658f183ab1f' | System           | 24 Aug 2020 04:47:09 |
| User entered 'None (0)'  | System           | 24 Aug 2020 04:47:09 |

US3222220

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:05:20

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b170983e9afc191a)', Time: '2020-08-24T00:46:43', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '8ca668e6-0148-4024-bfda-e658f183ab1f' | System           | 24 Aug 2020 04:47:09 |
| User entered 'None (0)'  | System           | 24 Aug 2020 04:47:09 |

US3222220

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:05:20

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b170983e9afc191a)', Time: '2020-08-24T00:46:50', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '8ca668e6-0148-4024-bfda-e658f183ab1f' | System           | 24 Aug 2020 04:47:09 |
| User entered 'None (0)'  | System           | 24 Aug 2020 04:47:09 |



US3222220

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:05:20

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b170983e9afc191a)', Time: '2020-08-24T00:46:53', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '8ca668e6-0148-4024-bfda-e658f183ab1f' | System           | 24 Aug 2020 04:47:09 |
| User entered 'None (0)'  | System           | 24 Aug 2020 04:47:09 |

US3222220

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:05:20

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b170983e9afc191a)', Time: '2020-08-24T00:46:57', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '8ca668e6-0148-4024-bfda-e658f183ab1f' | System           | 24 Aug 2020 04:47:09 |
| User entered 'None (0)'  | System           | 24 Aug 2020 04:47:09 |

US3222220

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:05:20

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b170983e9afc191a)', Time: '2020-08-24T00:46:59', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '8ca668e6-0148-4024-bfda-e658f183ab1f' | System           | 24 Aug 2020 04:47:09 |
| User entered 'None (0)'  | System           | 24 Aug 2020 04:47:09 |

US3222220

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:05:20

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) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b170983e9afc191a)', Time: '2020-08-24T00:47:03', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '8ca668e6-0148-4024-bfda-e658f183ab1f' | System           | 24 Aug 2020 04:47:09 |
| User entered 'No (N)'  | System           | 24 Aug 2020 04:47:09 |

US3222220

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:05:20

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b170983e9afc191a)', Time: '2020-08-24T00:47:07', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '8ca668e6-0148-4024-bfda-e658f183ab1f' | System           | 24 Aug 2020 04:47:09 |
| User entered '24 Aug 2020 00:47'   | System           | 24 Aug 2020 04:47:09 |

US3222220

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:05:20

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| User entered '23 Aug 2020 12:00' | System           | 19 Aug 2020 17:32:54 |

US3222220

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:05:20

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| User entered '24 Aug 2020 11:59' | System           | 19 Aug 2020 17:32:54 |

US3222220

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:05:20

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| Data entry locked.   | System           | 19 Aug 2020 17:32:54 |
| User entered 'Day 6' | System           | 19 Aug 2020 17:32:54 |



US3222220

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:05:20

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b170983e9afc191a)', Time: '2020-08-24T18:44:47', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: 'd69971c7-a7c7-45e2-a975-0ea196bc9c6c' | System           | 24 Aug 2020 22:45:16 |
| User entered 'None (0)'  | System           | 24 Aug 2020 22:45:16 |

US3222220

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:05:20

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b170983e9afc191a)', Time: '2020-08-24T18:44:50', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: 'd69971c7-a7c7-45e2-a975-0ea196bc9c6c' | System           | 24 Aug 2020 22:45:16 |
| User entered 'None (0)'  | System           | 24 Aug 2020 22:45:16 |

US3222220

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:05:20

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b170983e9afc191a)', Time: '2020-08-24T18:44:55', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: 'd69971c7-a7c7-45e2-a975-0ea196bc9c6c' | System           | 24 Aug 2020 22:45:16 |
| User entered 'None (0)'  | System           | 24 Aug 2020 22:45:16 |

US3222220

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:05:20

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b170983e9afc191a)', Time: '2020-08-24T18:44:58', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: 'd69971c7-a7c7-45e2-a975-0ea196bc9c6c' | System           | 24 Aug 2020 22:45:16 |
| User entered 'None (0)'  | System           | 24 Aug 2020 22:45:16 |

US3222220

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:05:20

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b170983e9afc191a)', Time: '2020-08-24T18:45:02', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: 'd69971c7-a7c7-45e2-a975-0ea196bc9c6c' | System           | 24 Aug 2020 22:45:16 |
| User entered 'None (0)'  | System           | 24 Aug 2020 22:45:16 |

US3222220

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:05:20

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b170983e9afc191a)', Time: '2020-08-24T18:45:06', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: 'd69971c7-a7c7-45e2-a975-0ea196bc9c6c' | System           | 24 Aug 2020 22:45:16 |
| User entered 'None (0)'  | System           | 24 Aug 2020 22:45:16 |

US3222220

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:05:20

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) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b170983e9afc191a)', Time: '2020-08-24T18:45:09', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: 'd69971c7-a7c7-45e2-a975-0ea196bc9c6c' | System           | 24 Aug 2020 22:45:16 |
| User entered 'No (N)'  | System           | 24 Aug 2020 22:45:16 |

US3222220

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:05:20

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b170983e9afc191a)', Time: '2020-08-24T18:45:13', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: 'd69971c7-a7c7-45e2-a975-0ea196bc9c6c' | System           | 24 Aug 2020 22:45:16 |
| User entered '24 Aug 2020 18:45'   | System           | 24 Aug 2020 22:45:16 |



US3222220

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:05:20

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| User entered '24 Aug 2020 12:00' | System           | 19 Aug 2020 17:32:54 |

US3222220

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:05:20

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| User entered '25 Aug 2020 11:59' | System           | 19 Aug 2020 17:32:54 |

US3222220

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:05:20

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| Data entry locked.   | System           | 19 Aug 2020 17:32:54 |
| User entered 'Day 7' | System           | 19 Aug 2020 17:32:54 |

US3222220

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:05:20

**HEADACHE**

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
|                   |                  |                      |

US3222220

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:05:20

**FATIGUE**

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
|                   |                  |                      |

US3222220

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:05:20

**MUSCLE ACHES ALL OVER BODY**

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
|                   |                  |                      |

US3222220

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:05:20

**JOINT ACHES IN SEVERAL JOINTS**

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
|                   |                  |                      |

US3222220

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:05:20

**NAUSEA/VOMITING**

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
|                   |                  |                      |



US3222220

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:05:20

**CHILLS**

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
|                   |                  |                      |

US3222220

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:05:20

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) | 05 Mar 2021 01:44:16 |
|                   |                  |                      |

US3222220

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:05:20

[PC Time stamp](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
|                   |                  |                      |

US3222220

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:05:20

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| User entered '25 Aug 2020 12:00' | System           | 19 Aug 2020 17:32:54 |

US3222220

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:05:20

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| User entered '26 Aug 2020 11:59' | System           | 19 Aug 2020 17:32:54 |

US3222220

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:20

[Was Contact Attempted?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 04 Apr 2021 18:17:07 |
| User signature succeeded. | Bruce Rankin (b) (4)  | 19 Feb 2021 22:18:05 |
| User entered 'Yes (Y)'    | Amber Vasquez (b) (4) | 05 Sep 2020 17:48:12 |

US3222220

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:20

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)      | 04 Apr 2021 18:17:07 |
| User signature succeeded.   | Bruce Rankin (b) (4)  | 19 Feb 2021 22:18:05 |
| User entered '26 Aug 2020' reason for change: Data Entry Error  | (b) (4)               |                      |
|   | (b) (4), (b) (6)      | 03 Dec 2020 13:32:40 |
| User closed query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).                                  | (b) (4), (b) (6)      | 28 Sep 2020 13:28:25 |
| Query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'data is correct as entered. ' (Site from System). | Amber Vasquez (b) (4) | 05 Sep 2020 17:49:10 |
|   | (b) (4)               |                      |
| User opened query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).                                  | System                | 05 Sep 2020 17:48:12 |
| User entered '30 Aug 2020'  | Amber Vasquez (b) (4) | 05 Sep 2020 17:48:12 |
|   | (b) (4)               |                      |

US3222220

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:20

[Please select one status for the follow-up contact](#)

| Audit   | User                             | Time (GMT)           |
|---|----------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                 | 04 Apr 2021 18:17:07 |
| User signature succeeded.   | Bruce Rankin (b) (4)             | 19 Feb 2021 22:18:05 |
| User entered 'Contact Made (CONTACT MADE)'<br>reason for change: Data Entry Error | (b) (4)<br>(b) (4), (b) (6)      | 03 Dec 2020 13:32:40 |
| User entered 'Contact Not Made (CONTACT NOT<br>MADE)'                             | Amber Vasquez (b) (4)<br>(b) (4) | 05 Sep 2020 17:48:12 |



US3222220

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:20

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit  | User                             | Time (GMT)           |
|--|----------------------------------|----------------------|
| Data hard locked.                                      | (b) (4), (b) (6)                 | 04 Apr 2021 18:17:07 |
| User signature succeeded.                              | Bruce Rankin (b) (4)             | 19 Feb 2021 22:18:05 |
| User entered empty; reason for change Data Entry Error | (b) (4)<br>(b) (4), (b) (6)      | 03 Dec 2020 13:32:40 |
| User entered 'LM for PT'                               | Amber Vasquez (b) (4)<br>(b) (4) | 05 Sep 2020 17:48:12 |

US3222220

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:20

[Is the participant continuing to the next visit?](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 04 Apr 2021 18:17:07 |
| User signature succeeded. | Bruce Rankin (b) (4)             | 19 Feb 2021 22:18:05 |
| User entered 'Yes (Y)'    | (b) (4)<br>Amber Vasquez (b) (4) | 05 Sep 2020 17:50:53 |

US3222220

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:20

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 18:17:07 |
| User entered 'I'  | System           | 05 Sep 2020 17:50:53 |

US3222220

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:20

[Was Contact Attempted?](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 04 Apr 2021 18:17:07 |
| User signature succeeded. | Bruce Rankin (b) (4)     | 19 Feb 2021 22:18:05 |
| User entered 'Yes (Y)'    | Jennifer Dittman (b) (4) | 17 Sep 2020 13:46:34 |

US3222220

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:20

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

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 04 Apr 2021 18:17:07 |
| User signature succeeded. | Bruce Rankin (b) (4)     | 19 Feb 2021 22:18:05 |
| User entered '2 Sep 2020' | Jennifer Dittman (b) (4) | 17 Sep 2020 13:46:34 |

US3222220

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:20

[Please select one status for the follow-up contact](#)

| Audit                                      | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)         | 04 Apr 2021 18:17:07 |
| User signature succeeded.                  | Bruce Rankin (b) (4)     | 19 Feb 2021 22:18:05 |
| User entered 'Contact Made (CONTACT MADE)' | Jennifer Dittman (b) (4) | 17 Sep 2020 13:46:34 |

US3222220

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:20

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 04 Apr 2021 18:17:07 |
| User signature succeeded. | Bruce Rankin (b) (4)     | 19 Feb 2021 22:18:05 |
| User entered empty.       | Jennifer Dittman (b) (4) | 17 Sep 2020 13:46:34 |

US3222220

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:20

[Is the participant continuing to the next visit?](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 04 Apr 2021 18:17:07 |
| User signature succeeded. | Bruce Rankin (b) (4)     | 19 Feb 2021 22:18:05 |
| User entered 'Yes (Y)'    | Jennifer Dittman (b) (4) | 17 Sep 2020 13:46:40 |



US3222220

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:20

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 18:17:07 |
| User entered 'I'  | System           | 17 Sep 2020 13:46:40 |

US3222220

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:20

[Was Contact Attempted?](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 04 Apr 2021 18:17:07 |
| User signature succeeded. | Bruce Rankin (b) (4)     | 19 Feb 2021 22:18:05 |
| User entered 'Yes (Y)'    | Jennifer Dittman (b) (4) | 17 Sep 2020 13:46:57 |

US3222220

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:20

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

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 04 Apr 2021 18:17:07 |
| User signature succeeded. | Bruce Rankin (b) (4)     | 19 Feb 2021 22:18:05 |
| User entered '9 Sep 2020' | Jennifer Dittman (b) (4) | 17 Sep 2020 13:46:57 |

US3222220

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:20

[Please select one status for the follow-up contact](#)

| Audit                                      | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)         | 04 Apr 2021 18:17:07 |
| User signature succeeded.                  | Bruce Rankin (b) (4)     | 19 Feb 2021 22:18:05 |
| User entered 'Contact Made (CONTACT MADE)' | Jennifer Dittman (b) (4) | 17 Sep 2020 13:46:57 |

US3222220

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:20

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 04 Apr 2021 18:17:07 |
| User signature succeeded. | Bruce Rankin (b) (4)     | 19 Feb 2021 22:18:05 |
| User entered empty.       | Jennifer Dittman (b) (4) | 17 Sep 2020 13:46:57 |

US3222220

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:20

[Is the participant continuing to the next visit?](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 04 Apr 2021 18:17:07 |
| User signature succeeded. | Bruce Rankin (b) (4)     | 19 Feb 2021 22:18:05 |
| User entered 'Yes (Y)'    | Jennifer Dittman (b) (4) | 17 Sep 2020 13:47:02 |

US3222220

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:20

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 18:17:07 |
| User entered 'I'  | System           | 17 Sep 2020 13:47:02 |

US3222220

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:05:20

[Was this visit performed?](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 04 Apr 2021 18:17:07 |
| User signature succeeded. | Bruce Rankin (b) (4)     | 19 Feb 2021 22:18:05 |
| User entered 'Yes (Y)'    | Jennifer Dittman (b) (4) | 17 Sep 2020 13:47:12 |



US3222220

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:05:20

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

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)         | 04 Apr 2021 18:17:07 |
| User signature succeeded.  | Bruce Rankin (b) (4)     | 19 Feb 2021 22:18:05 |
| User entered '17 Sep 2020' | Jennifer Dittman (b) (4) | 17 Sep 2020 13:47:12 |

US3222220

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:05:20

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

| Audit                          | User                     | Time (GMT)           |
|--------------------------------|--------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)         | 04 Apr 2021 18:17:07 |
| User signature succeeded.      | Bruce Rankin (b) (4)     | 19 Feb 2021 22:18:05 |
| User entered 'Clinic (Clinic)' | Jennifer Dittman (b) (4) | 17 Sep 2020 13:47:12 |

US3222220

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:05:20

[Folder OID](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 04 Apr 2021 18:17:07 |
| User entered 'VISIT2' | System           | 17 Sep 2020 13:47:12 |

US3222220

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:20

[Timepoint](#)

| Audit  | User                             | Time (GMT)           |
|--|----------------------------------|----------------------|
| Data hard locked.                                | (b) (4), (b) (6)                 | 04 Apr 2021 18:17:07 |
| User accepted default value 'Pre-Dose (PREDOSE)' | Albert Garcia (b) (4)<br>(b) (4) | 17 Sep 2020 15:31:51 |

US3222220

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:20

[Were vital signs assessed?](#)

| Audit                     | User  | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                            | 04 Apr 2021 18:17:07 |
| User signature succeeded. | Bruce Rankin (b) (4)                        | 19 Feb 2021 22:18:05 |
| User entered 'Yes (Y)'    | (b) (4)<br>Albert Garcia (b) (4)<br>(b) (4) | 17 Sep 2020 15:31:51 |

US3222220

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:20

Date of assessment (*dd MMM yyyy*)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 04 Apr 2021 18:17:07 |
| User signature succeeded.  | Bruce Rankin (b) (4)  | 19 Feb 2021 22:18:05 |
| User entered '17 Sep 2020' | Albert Garcia (b) (4) | 17 Sep 2020 15:31:51 |

US3222220

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:20

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

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 04 Apr 2021 18:17:07 |
| User signature succeeded. | Bruce Rankin (b) (4)  | 19 Feb 2021 22:18:05 |
| User entered '08:23'      | Albert Garcia (b) (4) | 17 Sep 2020 15:31:51 |

US3222220

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:20

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

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Apr 2021 18:17:07 |
| User entered '17 Sep 2020 08:23' | System           | 17 Sep 2020 15:31:51 |



US3222220

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:20

Temperature (xxx.x)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 04 Apr 2021 18:17:07 |
| User signature succeeded. | Bruce Rankin (b) (4)  | 19 Feb 2021 22:18:05 |
| User entered '37.1' C     | Albert Garcia (b) (4) | 17 Sep 2020 15:31:51 |

US3222220

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:20

[Route of measurement](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 04 Apr 2021 18:17:07 |
| User signature succeeded.  | Bruce Rankin (b) (4)  | 19 Feb 2021 22:18:05 |
| User entered 'Oral (Oral)' | Albert Garcia (b) (4) | 17 Sep 2020 15:31:51 |

US3222220

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:20

[If Other, specify](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 04 Apr 2021 18:17:07 |
| User signature succeeded. | Bruce Rankin (b) (4)  | 19 Feb 2021 22:18:05 |
| User entered empty.       | Albert Garcia (b) (4) | 17 Sep 2020 15:31:51 |

US3222220

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:20

[Pulse \(xxx\)](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 04 Apr 2021 18:17:07 |
| User signature succeeded. | Bruce Rankin (b) (4)  | 19 Feb 2021 22:18:05 |
| User entered '81'         | Albert Garcia (b) (4) | 17 Sep 2020 15:31:51 |

US3222220

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:20

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Apr 2021 18:17:07 |
| User entered 'bpm' | System           | 17 Sep 2020 15:31:51 |

US3222220

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:20

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

| Audit                     | User  | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                            | 04 Apr 2021 18:17:07 |
| User signature succeeded. | Bruce Rankin (b) (4)                        | 19 Feb 2021 22:18:05 |
| User entered '17'         | (b) (4)<br>Albert Garcia (b) (4)<br>(b) (4) | 17 Sep 2020 15:31:51 |

US3222220

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:20

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 04 Apr 2021 18:17:07 |
| User entered 'breaths/min' | System           | 17 Sep 2020 15:31:51 |

US3222220

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:20

Systolic Blood Pressure (xxx)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 04 Apr 2021 18:17:07 |
| User signature succeeded. | Bruce Rankin (b) (4)  | 19 Feb 2021 22:18:05 |
| User entered '150'        | Albert Garcia (b) (4) | 17 Sep 2020 15:31:51 |



US3222220

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:20

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Apr 2021 18:17:07 |
| User entered 'mmHg' | System           | 17 Sep 2020 15:31:51 |

US3222220

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:20

Diastolic Blood Pressure (xxx)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 04 Apr 2021 18:17:07 |
| User signature succeeded. | Bruce Rankin (b) (4)  | 19 Feb 2021 22:18:05 |
| User entered '98'         | Albert Garcia (b) (4) | 17 Sep 2020 15:31:51 |

US3222220

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:05:20

Diastolic Blood Pressure units

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Apr 2021 18:17:07 |
| User entered 'mmHg' | System           | 17 Sep 2020 15:31:51 |

US3222220

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:20

[Timepoint](#)

| Audit  | User                             | Time (GMT)           |
|--|----------------------------------|----------------------|
| Data hard locked.                                  | (b) (4), (b) (6)                 | 04 Apr 2021 18:17:07 |
| User accepted default value 'Post-Dose (POSTDOSE)' | Albert Garcia (b) (4)<br>(b) (4) | 17 Sep 2020 15:31:51 |

US3222220

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:20

[Were vital signs assessed?](#)

| Audit                     | User  | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                            | 04 Apr 2021 18:17:07 |
| User signature succeeded. | Bruce Rankin (b) (4)                        | 19 Feb 2021 22:18:05 |
| User entered 'Yes (Y)'    | (b) (4)<br>Albert Garcia (b) (4)<br>(b) (4) | 17 Sep 2020 15:31:51 |

US3222220

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:20

Date of assessment (*dd MMM yyyy*)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 04 Apr 2021 18:17:07 |
| User signature succeeded.  | Bruce Rankin (b) (4)  | 19 Feb 2021 22:18:05 |
| User entered '17 Sep 2020' | Albert Garcia (b) (4) | 17 Sep 2020 15:31:51 |

US3222220

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:20

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

| Audit                     | User  | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                            | 04 Apr 2021 18:17:07 |
| User signature succeeded. | Bruce Rankin (b) (4)                        | 19 Feb 2021 22:18:05 |
| User entered '10:15'      | (b) (4)<br>Albert Garcia (b) (4)<br>(b) (4) | 17 Sep 2020 15:31:51 |

US3222220

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:20

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

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Apr 2021 18:17:07 |
| User entered '17 Sep 2020 10:15' | System           | 17 Sep 2020 15:31:51 |



US3222220

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:20

Temperature (xxx.x)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 04 Apr 2021 18:17:07 |
| User signature succeeded. | Bruce Rankin (b) (4)  | 19 Feb 2021 22:18:05 |
| User entered '37.0' C     | Albert Garcia (b) (4) | 17 Sep 2020 15:31:51 |

US3222220

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:20

[Route of measurement](#)

| Audit                      | User  | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                            | 04 Apr 2021 18:17:07 |
| User signature succeeded.  | Bruce Rankin (b) (4)                        | 19 Feb 2021 22:18:05 |
| User entered 'Oral (Oral)' | (b) (4)<br>Albert Garcia (b) (4)<br>(b) (4) | 17 Sep 2020 15:31:51 |

US3222220

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:20

[If Other, specify](#)

| Audit                     | User  | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                            | 04 Apr 2021 18:17:07 |
| User signature succeeded. | Bruce Rankin (b) (4)                        | 19 Feb 2021 22:18:05 |
| User entered empty.       | (b) (4)<br>Albert Garcia (b) (4)<br>(b) (4) | 17 Sep 2020 15:31:51 |

US3222220

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:20

[Pulse \(xxx\)](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 04 Apr 2021 18:17:07 |
| User signature succeeded. | Bruce Rankin (b) (4)  | 19 Feb 2021 22:18:05 |
| User entered '70'         | Albert Garcia (b) (4) | 17 Sep 2020 15:31:51 |

US3222220

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:20

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Apr 2021 18:17:07 |
| User entered 'bpm' | System           | 17 Sep 2020 15:31:51 |

US3222220

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:20

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

| Audit                     | User  | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                            | 04 Apr 2021 18:17:07 |
| User signature succeeded. | Bruce Rankin (b) (4)                        | 19 Feb 2021 22:18:05 |
| User entered '18'         | (b) (4)<br>Albert Garcia (b) (4)<br>(b) (4) | 17 Sep 2020 15:31:51 |

US3222220

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:20

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 04 Apr 2021 18:17:07 |
| User entered 'breaths/min' | System           | 17 Sep 2020 15:31:51 |

US3222220

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:20

Systolic Blood Pressure (xxx)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 04 Apr 2021 18:17:07 |
| User signature succeeded. | Bruce Rankin (b) (4)  | 19 Feb 2021 22:18:05 |
| User entered '150'        | Albert Garcia (b) (4) | 17 Sep 2020 15:31:51 |



US3222220

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:20

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Apr 2021 18:17:07 |
| User entered 'mmHg' | System           | 17 Sep 2020 15:31:51 |

US3222220

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:20

Diastolic Blood Pressure (xxx)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 04 Apr 2021 18:17:07 |
| User signature succeeded. | Bruce Rankin (b) (4)  | 19 Feb 2021 22:18:05 |
| User entered '90'         | Albert Garcia (b) (4) | 17 Sep 2020 15:31:51 |

US3222220

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:05:20

Diastolic Blood Pressure units

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Apr 2021 18:17:07 |
| User entered 'mmHg' | System           | 17 Sep 2020 15:31:51 |

US3222220

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:05:20

[Was the physical examination performed?](#)

| Audit                     | User  | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                            | 04 Apr 2021 18:17:07 |
| User signature succeeded. | Bruce Rankin (b) (4)                        | 19 Feb 2021 22:18:05 |
| User entered 'Yes (Y)'    | (b) (4)<br>Albert Garcia (b) (4)<br>(b) (4) | 17 Sep 2020 15:31:59 |

US3222220

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:05:20

Date of examination (dd MMM yyyy)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 04 Apr 2021 18:17:07 |
| User signature succeeded.  | Bruce Rankin (b) (4)  | 19 Feb 2021 22:18:05 |
| User entered '17 Sep 2020' | Albert Garcia (b) (4) | 17 Sep 2020 15:31:59 |

US3222220

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:05:20

[Was study treatment given?](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 04 Apr 2021 18:17:07 |
| User signature succeeded. | Bruce Rankin (b) (4)     | 19 Feb 2021 22:18:05 |
| User entered 'Yes (Y)'    | Jennifer Dittman (b) (4) | 17 Sep 2020 13:47:37 |

US3222220

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:05:20

[If No, reason not given](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 04 Apr 2021 18:17:07 |
| User signature succeeded. | Bruce Rankin (b) (4)     | 19 Feb 2021 22:18:05 |
| User entered empty.       | Jennifer Dittman (b) (4) | 17 Sep 2020 13:47:37 |

US3222220

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:05:20

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)         | 04 Apr 2021 18:17:07 |
| User signature succeeded. | Bruce Rankin (b) (4)     | 19 Feb 2021 22:18:05 |
| User entered empty.       | Jennifer Dittman (b) (4) | 17 Sep 2020 13:47:37 |



US3222220

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:05:20

[What was the study treatment?](#)

| Audit                               | User             | Time (GMT)           |
|-------------------------------------|------------------|----------------------|
| Data hard locked.                   | (b) (4), (b) (6) | 04 Apr 2021 18:17:07 |
| User entered 'MRNA-1273 OR PLACEBO' | System           | 17 Sep 2020 13:47:37 |

US3222220

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:05:20

What was the treatment date? (dd MMM yyyy)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)         | 04 Apr 2021 18:17:07 |
| User signature succeeded.  | Bruce Rankin (b) (4)     | 19 Feb 2021 22:18:05 |
| User entered '17 Sep 2020' | Jennifer Dittman (b) (4) | 17 Sep 2020 13:47:37 |

US3222220

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:05:20

[What was the treatment time? \(00:00-23:59\)](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 04 Apr 2021 18:17:07 |
| User signature succeeded. | Bruce Rankin (b) (4)     | 19 Feb 2021 22:18:05 |
| User entered '09:32'      | Jennifer Dittman (b) (4) | 17 Sep 2020 13:47:37 |

US3222220

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:05:20

[Treatment Date and Time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Apr 2021 18:17:07 |
| User entered '17 Sep 2020 09:32' | System           | 17 Sep 2020 13:47:37 |

US3222220

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:05:20

[Which arm was used to give treatment?](#)

| Audit                                | User                     | Time (GMT)           |
|--------------------------------------|--------------------------|----------------------|
| Data hard locked.                    | (b) (4), (b) (6)         | 04 Apr 2021 18:17:07 |
| User signature succeeded.            | Bruce Rankin (b) (4)     | 19 Feb 2021 22:18:05 |
| User entered 'Right Arm (RIGHT ARM)' | Jennifer Dittman (b) (4) | 17 Sep 2020 13:47:37 |

US3222220

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:05:20

[What was the frequency of the study treatment dosing?](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Apr 2021 18:17:07 |
| User entered 'ONCE' | System           | 17 Sep 2020 13:47:37 |

US3222220

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:05:20

What was the route of administration for the study treatment?

| Audit                        | User             | Time (GMT)           |
|------------------------------|------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6) | 04 Apr 2021 18:17:07 |
| User entered 'INTRAMUSCULAR' | System           | 17 Sep 2020 13:47:37 |

US3222220

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:20

[Was the sample collected?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 04 Apr 2021 18:17:07 |
| User signature succeeded. | Bruce Rankin (b) (4)  | 19 Feb 2021 22:18:05 |
| User entered 'Yes (Y)'    | Albert Garcia (b) (4) | 17 Sep 2020 15:32:17 |



US3222220

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:20

Collection date (dd MMM yyyy)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 04 Apr 2021 18:17:07 |
| User signature succeeded.  | Bruce Rankin (b) (4)  | 19 Feb 2021 22:18:05 |
| User entered '17 Sep 2020' | Albert Garcia (b) (4) | 17 Sep 2020 15:32:17 |

US3222220

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:20

Collection time (00:00-23:59)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 04 Apr 2021 18:17:07 |
| User signature succeeded. | Bruce Rankin (b) (4)  | 19 Feb 2021 22:18:05 |
| User entered '08:55'      | Albert Garcia (b) (4) | 17 Sep 2020 15:32:17 |

US3222220

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:20

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

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Apr 2021 18:17:07 |
| User entered '17 Sep 2020 08:55' | System           | 17 Sep 2020 15:32:17 |

US3222220

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:05:20

Collection date (dd MMM yyyy)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 04 Apr 2021 18:17:07 |
| User signature succeeded.  | Bruce Rankin (b) (4)  | 19 Feb 2021 22:18:05 |
| User entered '17 Sep 2020' | Albert Garcia (b) (4) | 17 Sep 2020 15:32:33 |

US3222220

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:05:20

[Lab Test](#)

| Audit  | User                             | Time (GMT)           |
|--|----------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                 | 04 Apr 2021 18:17:07 |
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | Albert Garcia (b) (4)<br>(b) (4) | 17 Sep 2020 15:32:33 |

US3222220

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:05:20

[Was the sample collected?](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 04 Apr 2021 18:17:07 |
| User signature succeeded. | Bruce Rankin (b) (4)             | 19 Feb 2021 22:18:05 |
| User entered 'Yes (Y)'    | (b) (4)<br>Albert Garcia (b) (4) | 17 Sep 2020 15:32:33 |

US3222220

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:05:20

Collection time (00:00 - 23:59)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 04 Apr 2021 18:17:07 |
| User signature succeeded. | Bruce Rankin (b) (4)  | 19 Feb 2021 22:18:05 |
| User entered '08:57'      | Albert Garcia (b) (4) | 17 Sep 2020 15:32:33 |

**US3222220**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 16:05:20**

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

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Apr 2021 18:17:07 |
| User entered '17 Sep 2020 08:57' | System           | 17 Sep 2020 15:32:33 |



US3222220

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:05:20

[Lab Test](#)

| Audit  | User                             | Time (GMT)           |
|--|----------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                 | 04 Apr 2021 18:17:07 |
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | Albert Garcia (b) (4)<br>(b) (4) | 17 Sep 2020 15:32:33 |

US3222220

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:05:20

[Was the sample collected?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 04 Apr 2021 18:17:07 |
| User signature succeeded. | Bruce Rankin (b) (4)  | 19 Feb 2021 22:18:05 |
| User entered 'No (N)'     | Albert Garcia (b) (4) | 17 Sep 2020 15:32:33 |

US3222220

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:05:20

Collection time (00:00 - 23:59)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 04 Apr 2021 18:17:07 |
| User signature succeeded. | Bruce Rankin (b) (4)  | 19 Feb 2021 22:18:05 |
| User entered empty.       | Albert Garcia (b) (4) | 17 Sep 2020 15:32:33 |

US3222220

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:05:20

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Apr 2021 18:17:07 |
| User entered empty. | System           | 17 Sep 2020 15:32:33 |

US3222220

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:20

[Is the participant continuing to the next visit?](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 04 Apr 2021 18:17:07 |
| User signature succeeded. | Bruce Rankin (b) (4)     | 19 Feb 2021 22:18:05 |
| User entered 'Yes (Y)'    | Jennifer Dittman (b) (4) | 17 Sep 2020 13:47:50 |

US3222220

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:20

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 18:17:07 |
| User entered '1'  | System           | 17 Sep 2020 13:47:50 |

US3222220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:05:20

**TIMEPOINT**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| Data entry locked.   | System           | 17 Sep 2020 13:47:37 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System           | 17 Sep 2020 13:47:37 |

US3222220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:05:20

Was **TEMPERATURE** taken?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-17T10:14:51', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '72abafdd-4c80-4b67-8509-52ca69094ef5' | System           | 17 Sep 2020 14:15:18 |
| User entered 'Yes (Y)'   | System           | 17 Sep 2020 14:15:18 |



US3222220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:05:20

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-17T10:15:00', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '72abafdd-4c80-4b67-8509-52ca69094ef5' | System           | 17 Sep 2020 14:15:18 |
| User entered '98.6'  | System           | 17 Sep 2020 14:15:18 |

US3222220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:05:20

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-17T10:15:04', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '72abafdd-4c80-4b67-8509-52ca69094ef5' | System           | 17 Sep 2020 14:15:18 |
| User entered 'No (N)'  | System           | 17 Sep 2020 14:15:18 |

US3222220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:05:20

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-17T10:15:10', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '72abafdd-4c80-4b67-8509-52ca69094ef5' | System           | 17 Sep 2020 14:15:18 |
| User entered '17 Sep 2020 10:15'   | System           | 17 Sep 2020 14:15:18 |

US3222220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:05:20

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| User entered '17 Sep 2020 09:52' | System           | 17 Sep 2020 13:47:37 |

US3222220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:05:20

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| User entered '17 Sep 2020 12:22' | System           | 17 Sep 2020 13:47:37 |

US3222220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:05:20

**TIMEPOINT**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| Data entry locked.                                | System           | 17 Sep 2020 13:47:37 |
| User entered 'Day 1, after vaccination (at home)' | System           | 17 Sep 2020 13:47:37 |

US3222220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:05:20

Was **TEMPERATURE** taken?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-17T20:38:16', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '7d841703-071f-48ea-a7c6-6baf261a231b' | System           | 18 Sep 2020 00:38:46 |
| User entered 'Yes (Y)'   | System           | 18 Sep 2020 00:38:46 |

US3222220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:05:20

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-17T20:38:01', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '7d841703-071f-48ea-a7c6-6baf261a231b' | System           | 18 Sep 2020 00:38:46 |
| User entered '98.5'  | System           | 18 Sep 2020 00:38:46 |



US3222220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:05:20

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-17T20:38:08', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '7d841703-071f-48ea-a7c6-6baf261a231b' | System           | 18 Sep 2020 00:38:46 |
| User entered 'No (N)'  | System           | 18 Sep 2020 00:38:46 |

US3222220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:05:20

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-17T20:38:20', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '7d841703-071f-48ea-a7c6-6baf261a231b' | System           | 18 Sep 2020 00:38:46 |
| User entered '17 Sep 2020 20:38'   | System           | 18 Sep 2020 00:38:46 |

US3222220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:05:20

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| User entered '17 Sep 2020 13:17' | System           | 17 Sep 2020 13:47:37 |

US3222220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:05:20

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| User entered '18 Sep 2020 11:59' | System           | 17 Sep 2020 13:47:37 |

US3222220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:05:20

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| Data entry locked.   | System           | 17 Sep 2020 13:47:37 |
| User entered 'Day 2' | System           | 17 Sep 2020 13:47:37 |

US3222220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:05:20

Was **TEMPERATURE** taken?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-18T19:28:23', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '82a8904b-8e7b-4010-acb4-aa092fc7a9c7' | System           | 18 Sep 2020 23:28:49 |
| User entered 'Yes (Y)'   | System           | 18 Sep 2020 23:28:49 |

US3222220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:05:20

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-18T19:28:31', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '82a8904b-8e7b-4010-acb4-aa092fc7a9c7' | System           | 18 Sep 2020 23:28:49 |
| User entered '96.9'  | System           | 18 Sep 2020 23:28:49 |

US3222220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:05:20

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-18T19:28:35', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '82a8904b-8e7b-4010-acb4-aa092fc7a9c7' | System           | 18 Sep 2020 23:28:49 |
| User entered 'No (N)'  | System           | 18 Sep 2020 23:28:49 |



US3222220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:05:20

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-18T19:28:43', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '82a8904b-8e7b-4010-acb4-aa092fc7a9c7' | System           | 18 Sep 2020 23:28:49 |
| User entered '18 Sep 2020 19:28'   | System           | 18 Sep 2020 23:28:49 |

US3222220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:05:20

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| User entered '18 Sep 2020 12:00' | System           | 17 Sep 2020 13:47:37 |

US3222220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:05:20

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| User entered '19 Sep 2020 11:59' | System           | 17 Sep 2020 13:47:37 |

US3222220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:05:20

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| Data entry locked.   | System           | 17 Sep 2020 13:47:37 |
| User entered 'Day 3' | System           | 17 Sep 2020 13:47:37 |

US3222220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:05:20

Was **TEMPERATURE** taken?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-19T12:01:35', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: 'f6f3d215-2a69-43e1-8e92-0c36dd75dfff' | System           | 19 Sep 2020 16:02:26 |
| User entered 'Yes (Y)'   | System           | 19 Sep 2020 16:02:26 |

US3222220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:05:20

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-19T12:01:46', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: 'f6f3d215-2a69-43e1-8e92-0c36dd75dfff' | System           | 19 Sep 2020 16:02:26 |
| User entered '98.9'  | System           | 19 Sep 2020 16:02:26 |

US3222220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:05:20

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-19T12:01:49', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: 'f6f3d215-2a69-43e1-8e92-0c36dd75dfff' | System           | 19 Sep 2020 16:02:26 |
| User entered 'No (N)'  | System           | 19 Sep 2020 16:02:26 |

US3222220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:05:20

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-19T12:01:58', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: 'f6f3d215-2a69-43e1-8e92-0c36dd75dfff' | System           | 19 Sep 2020 16:02:26 |
| User entered '19 Sep 2020 12:01'   | System           | 19 Sep 2020 16:02:26 |



US3222220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:05:20

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| User entered '19 Sep 2020 12:00' | System           | 17 Sep 2020 13:47:37 |

US3222220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:05:20

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| User entered '20 Sep 2020 11:59' | System           | 17 Sep 2020 13:47:37 |

US3222220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:05:20

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| Data entry locked.   | System           | 17 Sep 2020 13:47:37 |
| User entered 'Day 4' | System           | 17 Sep 2020 13:47:37 |

US3222220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:05:20

Was **TEMPERATURE** taken?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-20T12:02:17', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: 'c517b07d-e01f-4e53-87b6-7f70f976dc97' | System           | 20 Sep 2020 16:03:19 |
| User entered 'Yes (Y)'   | System           | 20 Sep 2020 16:03:19 |

US3222220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:05:20

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-20T12:02:25', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: 'c517b07d-e01f-4e53-87b6-7f70f976dc97' | System           | 20 Sep 2020 16:03:19 |
| User entered '98.5'  | System           | 20 Sep 2020 16:03:19 |

US3222220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:05:20

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-20T12:02:30', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: 'c517b07d-e01f-4e53-87b6-7f70f976dc97' | System           | 20 Sep 2020 16:03:19 |
| User entered 'No (N)'  | System           | 20 Sep 2020 16:03:19 |

US3222220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:05:20

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-20T12:02:34', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: 'c517b07d-e01f-4e53-87b6-7f70f976dc97' | System           | 20 Sep 2020 16:03:19 |
| User entered '20 Sep 2020 12:02'   | System           | 20 Sep 2020 16:03:19 |

US3222220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:05:20

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| User entered '20 Sep 2020 12:00' | System           | 17 Sep 2020 13:47:37 |



US3222220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:05:20

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| User entered '21 Sep 2020 11:59' | System           | 17 Sep 2020 13:47:37 |

US3222220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:05:20

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| Data entry locked.   | System           | 17 Sep 2020 13:47:37 |
| User entered 'Day 5' | System           | 17 Sep 2020 13:47:37 |

US3222220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:05:20

Was **TEMPERATURE** taken?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-21T12:05:01', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '9a3464c4-cd5d-4f3c-8d01-ad387ead479b' | System           | 21 Sep 2020 16:18:49 |
| User entered 'Yes (Y)'   | System           | 21 Sep 2020 16:18:49 |

US3222220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:05:20

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-21T12:05:06', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '9a3464c4-cd5d-4f3c-8d01-ad387ead479b' | System           | 21 Sep 2020 16:18:49 |
| User entered '99.1'  | System           | 21 Sep 2020 16:18:49 |

US3222220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:05:20

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-21T12:05:09', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '9a3464c4-cd5d-4f3c-8d01-ad387ead479b' | System           | 21 Sep 2020 16:18:49 |
| User entered 'No (N)'  | System           | 21 Sep 2020 16:18:49 |

US3222220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:05:20

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-21T12:05:13', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '9a3464c4-cd5d-4f3c-8d01-ad387ead479b' | System           | 21 Sep 2020 16:18:49 |
| User entered '21 Sep 2020 12:05'   | System           | 21 Sep 2020 16:18:49 |

US3222220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:05:20

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| User entered '21 Sep 2020 12:00' | System           | 17 Sep 2020 13:47:37 |

US3222220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:05:20

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| User entered '22 Sep 2020 11:59' | System           | 17 Sep 2020 13:47:37 |



US3222220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:05:20

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| Data entry locked.   | System           | 17 Sep 2020 13:47:37 |
| User entered 'Day 6' | System           | 17 Sep 2020 13:47:37 |

US3222220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:05:20

Was **TEMPERATURE** taken?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-22T12:03:14', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: 'c0d29838-c1ea-4b0d-b127-9527b8c6dc2e' | System           | 22 Sep 2020 16:04:34 |
| User entered 'Yes (Y)'   | System           | 22 Sep 2020 16:04:34 |

US3222220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:05:20

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-22T12:03:22', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: 'c0d29838-c1ea-4b0d-b127-9527b8c6dc2e' | System           | 22 Sep 2020 16:04:34 |
| User entered '98.8'  | System           | 22 Sep 2020 16:04:34 |

US3222220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:05:20

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-22T12:03:26', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: 'c0d29838-c1ea-4b0d-b127-9527b8c6dc2e' | System           | 22 Sep 2020 16:04:34 |
| User entered 'No (N)'  | System           | 22 Sep 2020 16:04:34 |

US3222220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:05:20

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-22T12:03:30', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: 'c0d29838-c1ea-4b0d-b127-9527b8c6dc2e' | System           | 22 Sep 2020 16:04:34 |
| User entered '22 Sep 2020 12:03'   | System           | 22 Sep 2020 16:04:34 |

US3222220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:05:20

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| User entered '22 Sep 2020 12:00' | System           | 17 Sep 2020 13:47:37 |

US3222220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:05:20

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| User entered '23 Sep 2020 11:59' | System           | 17 Sep 2020 13:47:37 |

US3222220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:05:20

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| Data entry locked.   | System           | 17 Sep 2020 13:47:37 |
| User entered 'Day 7' | System           | 17 Sep 2020 13:47:37 |



US3222220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:05:20

Was **TEMPERATURE** taken?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-23T15:09:29', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '6509c425-052b-4698-b1b8-b00f1be71cb0' | System           | 23 Sep 2020 19:09:46 |
| User entered 'Yes (Y)'   | System           | 23 Sep 2020 19:09:46 |

US3222220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:05:20

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-23T15:09:36', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '6509c425-052b-4698-b1b8-b00f1be71cb0' | System           | 23 Sep 2020 19:09:46 |
| User entered '98.8'  | System           | 23 Sep 2020 19:09:46 |

US3222220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:05:20

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-23T15:09:40', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '6509c425-052b-4698-b1b8-b00f1be71cb0' | System           | 23 Sep 2020 19:09:46 |
| User entered 'No (N)'  | System           | 23 Sep 2020 19:09:46 |

US3222220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:05:20

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-23T15:09:43', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '6509c425-052b-4698-b1b8-b00f1be71cb0' | System           | 23 Sep 2020 19:09:46 |
| User entered '23 Sep 2020 15:09'   | System           | 23 Sep 2020 19:09:46 |

US3222220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:05:20

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| User entered '23 Sep 2020 12:00' | System           | 17 Sep 2020 13:47:37 |

US3222220

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:05:20

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| User entered '24 Sep 2020 11:59' | System           | 17 Sep 2020 13:47:37 |

US3222220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:05:20

**TIMEPOINT**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| Data entry locked.   | System           | 17 Sep 2020 13:47:37 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System           | 17 Sep 2020 13:47:37 |

US3222220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:05:20

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-17T10:15:31', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '3e6dd81a-73d9-43b4-a5bd-c9d362c8d9b5' | System           | 17 Sep 2020 14:15:55 |
| User entered 'None (1)'  | System           | 17 Sep 2020 14:15:55 |



US3222220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:05:20

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-17T10:15:34', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '3e6dd81a-73d9-43b4-a5bd-c9d362c8d9b5' | System           | 17 Sep 2020 14:15:55 |
| User entered 'No (N)'  | System           | 17 Sep 2020 14:15:55 |

US3222220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:05:20

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-17T10:15:37', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '3e6dd81a-73d9-43b4-a5bd-c9d362c8d9b5' | System           | 17 Sep 2020 14:15:55 |
| User entered 'No (N)'  | System           | 17 Sep 2020 14:15:55 |

US3222220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:05:20

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-17T10:15:47', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '3e6dd81a-73d9-43b4-a5bd-c9d362c8d9b5' | System           | 17 Sep 2020 14:15:55 |
| User entered 'None (1)'  | System           | 17 Sep 2020 14:15:55 |

US3222220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:05:20

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-17T10:15:52', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '3e6dd81a-73d9-43b4-a5bd-c9d362c8d9b5' | System           | 17 Sep 2020 14:15:55 |
| User entered '17 Sep 2020 10:15'   | System           | 17 Sep 2020 14:15:55 |

US3222220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:05:20

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| User entered '17 Sep 2020 09:52' | System           | 17 Sep 2020 13:47:37 |

US3222220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:05:20

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| User entered '17 Sep 2020 12:22' | System           | 17 Sep 2020 13:47:37 |

US3222220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:05:20

**TIMEPOINT**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| Data entry locked.                                | System           | 17 Sep 2020 13:47:37 |
| User entered 'Day 1, after vaccination (at home)' | System           | 17 Sep 2020 13:47:37 |

US3222220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:05:20

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-17T20:38:47', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '8aeacef0-9635-4d44-9f28-774f3188cbb3' | System           | 18 Sep 2020 00:38:59 |
| User entered 'None (1)'  | System           | 18 Sep 2020 00:38:59 |



US3222220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:05:20

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-17T20:38:33', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '8aeacef0-9635-4d44-9f28-774f3188cbb3' | System           | 18 Sep 2020 00:38:59 |
| User entered 'No (N)'  | System           | 18 Sep 2020 00:38:59 |

US3222220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:05:20

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-17T20:38:36', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '8aeacef0-9635-4d44-9f28-774f3188cbb3' | System           | 18 Sep 2020 00:38:59 |
| User entered 'No (N)'  | System           | 18 Sep 2020 00:38:59 |

US3222220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:05:20

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-17T20:38:41', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '8aeacef0-9635-4d44-9f28-774f3188cbb3' | System           | 18 Sep 2020 00:38:59 |
| User entered 'None (1)'  | System           | 18 Sep 2020 00:38:59 |

US3222220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:05:20

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-17T20:38:50', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '8aeacef0-9635-4d44-9f28-774f3188cbb3' | System           | 18 Sep 2020 00:38:59 |
| User entered '17 Sep 2020 20:38'   | System           | 18 Sep 2020 00:38:59 |

US3222220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:05:20

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| User entered '17 Sep 2020 13:17' | System           | 17 Sep 2020 13:47:37 |

US3222220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:05:20

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| User entered '18 Sep 2020 11:59' | System           | 17 Sep 2020 13:47:37 |

US3222220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:05:20

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| Data entry locked.   | System           | 17 Sep 2020 13:47:37 |
| User entered 'Day 2' | System           | 17 Sep 2020 13:47:37 |

US3222220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:05:20

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-18T19:29:10', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: 'f1c59510-d285-4e8c-9354-935c2235bc26' | System           | 18 Sep 2020 23:29:35 |
| User entered 'None (1)'  | System           | 18 Sep 2020 23:29:35 |



US3222220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:05:20

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-18T19:29:17', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: 'f1c59510-d285-4e8c-9354-935c2235bc26' | System           | 18 Sep 2020 23:29:35 |
| User entered 'No (N)'  | System           | 18 Sep 2020 23:29:35 |

US3222220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:05:20

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-18T19:29:20', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: 'f1c59510-d285-4e8c-9354-935c2235bc26' | System           | 18 Sep 2020 23:29:35 |
| User entered 'No (N)'  | System           | 18 Sep 2020 23:29:35 |

US3222220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:05:20

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-18T19:29:25', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: 'f1c59510-d285-4e8c-9354-935c2235bc26' | System           | 18 Sep 2020 23:29:35 |
| User entered 'None (1)'  | System           | 18 Sep 2020 23:29:35 |

US3222220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:05:20

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-18T19:29:30', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: 'f1c59510-d285-4e8c-9354-935c2235bc26' | System           | 18 Sep 2020 23:29:35 |
| User entered '18 Sep 2020 19:29'   | System           | 18 Sep 2020 23:29:35 |

US3222220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:05:20

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| User entered '18 Sep 2020 12:00' | System           | 17 Sep 2020 13:47:37 |

US3222220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:05:20

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| User entered '19 Sep 2020 11:59' | System           | 17 Sep 2020 13:47:37 |

US3222220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:05:20

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| Data entry locked.   | System           | 17 Sep 2020 13:47:37 |
| User entered 'Day 3' | System           | 17 Sep 2020 13:47:37 |

US3222220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:05:20

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-19T12:02:05', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: 'aa3e3de0-3ce2-4657-ad73-11697abc93c8' | System           | 19 Sep 2020 16:02:50 |
| User entered 'None (1)'  | System           | 19 Sep 2020 16:02:50 |



US3222220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:05:20

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-19T12:02:08', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: 'aa3e3de0-3ce2-4657-ad73-11697abc93c8' | System           | 19 Sep 2020 16:02:50 |
| User entered 'No (N)'  | System           | 19 Sep 2020 16:02:50 |

US3222220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:05:20

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-19T12:02:12', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: 'aa3e3de0-3ce2-4657-ad73-11697abc93c8' | System           | 19 Sep 2020 16:02:50 |
| User entered 'No (N)'  | System           | 19 Sep 2020 16:02:50 |

US3222220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:05:20

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-19T12:02:16', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: 'aa3e3de0-3ce2-4657-ad73-11697abc93c8' | System           | 19 Sep 2020 16:02:50 |
| User entered 'None (1)'  | System           | 19 Sep 2020 16:02:50 |

US3222220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:05:20

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-19T12:02:22', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: 'aa3e3de0-3ce2-4657-ad73-11697abc93c8' | System           | 19 Sep 2020 16:02:50 |
| User entered '19 Sep 2020 12:02'   | System           | 19 Sep 2020 16:02:50 |

US3222220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:05:20

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| User entered '19 Sep 2020 12:00' | System           | 17 Sep 2020 13:47:37 |

US3222220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:05:20

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| User entered '20 Sep 2020 11:59' | System           | 17 Sep 2020 13:47:37 |

US3222220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:05:20

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| Data entry locked.   | System           | 17 Sep 2020 13:47:37 |
| User entered 'Day 4' | System           | 17 Sep 2020 13:47:37 |

US3222220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:05:20

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-20T12:02:42', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: 'c530ac5c-d32f-4b63-8fce-b3d86fe2cfa8' | System           | 20 Sep 2020 16:03:55 |
| User entered 'None (1)'  | System           | 20 Sep 2020 16:03:55 |



US3222220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:05:20

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-20T12:02:45', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: 'c530ac5c-d32f-4b63-8fce-b3d86fe2cfa8' | System           | 20 Sep 2020 16:03:55 |
| User entered 'No (N)'  | System           | 20 Sep 2020 16:03:55 |

US3222220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:05:20

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-20T12:02:48', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: 'c530ac5c-d32f-4b63-8fce-b3d86fe2cfa8' | System           | 20 Sep 2020 16:03:55 |
| User entered 'No (N)'  | System           | 20 Sep 2020 16:03:55 |

US3222220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:05:20

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-20T12:02:53', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: 'c530ac5c-d32f-4b63-8fce-b3d86fe2cfa8' | System           | 20 Sep 2020 16:03:55 |
| User entered 'None (1)'  | System           | 20 Sep 2020 16:03:55 |

US3222220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:05:20

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-20T12:03:21', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: 'c530ac5c-d32f-4b63-8fce-b3d86fe2cfa8' | System           | 20 Sep 2020 16:03:55 |
| User entered '20 Sep 2020 12:03'   | System           | 20 Sep 2020 16:03:55 |

US3222220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:05:20

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| User entered '20 Sep 2020 12:00' | System           | 17 Sep 2020 13:47:37 |

US3222220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:05:20

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| User entered '21 Sep 2020 11:59' | System           | 17 Sep 2020 13:47:37 |

US3222220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:05:20

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| Data entry locked.   | System           | 17 Sep 2020 13:47:37 |
| User entered 'Day 5' | System           | 17 Sep 2020 13:47:37 |

US3222220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:05:20

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-21T12:05:19', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '643d9b7a-b684-4f12-a9f8-f8e9ab20b66e' | System           | 21 Sep 2020 16:19:00 |
| User entered 'None (1)'  | System           | 21 Sep 2020 16:19:00 |



US3222220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:05:20

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-21T12:05:23', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '643d9b7a-b684-4f12-a9f8-f8e9ab20b66e' | System           | 21 Sep 2020 16:19:00 |
| User entered 'No (N)'  | System           | 21 Sep 2020 16:19:00 |

US3222220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:05:20

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-21T12:05:26', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '643d9b7a-b684-4f12-a9f8-f8e9ab20b66e' | System           | 21 Sep 2020 16:19:00 |
| User entered 'No (N)'  | System           | 21 Sep 2020 16:19:00 |

US3222220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:05:20

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-21T12:05:30', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '643d9b7a-b684-4f12-a9f8-f8e9ab20b66e' | System           | 21 Sep 2020 16:19:00 |
| User entered 'None (1)'  | System           | 21 Sep 2020 16:19:00 |

US3222220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:05:20

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-21T12:05:34', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '643d9b7a-b684-4f12-a9f8-f8e9ab20b66e' | System           | 21 Sep 2020 16:19:00 |
| User entered '21 Sep 2020 12:05'   | System           | 21 Sep 2020 16:19:00 |

US3222220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:05:20

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| User entered '21 Sep 2020 12:00' | System           | 17 Sep 2020 13:47:37 |

US3222220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:05:20

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| User entered '22 Sep 2020 11:59' | System           | 17 Sep 2020 13:47:37 |

US3222220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:05:20

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| Data entry locked.   | System           | 17 Sep 2020 13:47:37 |
| User entered 'Day 6' | System           | 17 Sep 2020 13:47:37 |

US3222220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:05:20

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-22T12:03:37', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: 'bece6f95-746c-42c7-a5d2-fd7ddbf7db98' | System           | 22 Sep 2020 16:04:49 |
| User entered 'None (1)'  | System           | 22 Sep 2020 16:04:49 |



US3222220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:05:20

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

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-22T12:03:41', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: 'bece6f95-746c-42c7-a5d2-fd7ddb7db98' | System           | 22 Sep 2020 16:04:49 |
| User entered 'No (N)'   | System           | 22 Sep 2020 16:04:49 |

US3222220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:05:20

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-22T12:03:44', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: 'bece6f95-746c-42c7-a5d2-fd7ddbf7db98' | System           | 22 Sep 2020 16:04:49 |
| User entered 'No (N)'  | System           | 22 Sep 2020 16:04:49 |

US3222220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:05:20

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-22T12:03:48', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: 'bece6f95-746c-42c7-a5d2-fd7ddbf7db98' | System           | 22 Sep 2020 16:04:49 |
| User entered 'None (1)'  | System           | 22 Sep 2020 16:04:49 |

US3222220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:05:20

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-22T12:03:53', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: 'bece6f95-746c-42c7-a5d2-fd7ddb7db98' | System           | 22 Sep 2020 16:04:49 |
| User entered '22 Sep 2020 12:03'  | System           | 22 Sep 2020 16:04:49 |

US3222220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:05:20

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| User entered '22 Sep 2020 12:00' | System           | 17 Sep 2020 13:47:37 |

US3222220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:05:20

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| User entered '23 Sep 2020 11:59' | System           | 17 Sep 2020 13:47:37 |

US3222220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:05:20

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| Data entry locked.   | System           | 17 Sep 2020 13:47:37 |
| User entered 'Day 7' | System           | 17 Sep 2020 13:47:37 |

US3222220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:05:20

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-23T15:09:48', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '32d249c6-f5c9-48f6-a903-2f5db12918d3' | System           | 23 Sep 2020 19:10:10 |
| User entered 'None (1)'  | System           | 23 Sep 2020 19:10:10 |



US3222220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:05:20

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-23T15:09:52', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '32d249c6-f5c9-48f6-a903-2f5db12918d3' | System           | 23 Sep 2020 19:10:10 |
| User entered 'No (N)'  | System           | 23 Sep 2020 19:10:10 |

US3222220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:05:20

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-23T15:09:56', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '32d249c6-f5c9-48f6-a903-2f5db12918d3' | System           | 23 Sep 2020 19:10:10 |
| User entered 'No (N)'  | System           | 23 Sep 2020 19:10:10 |

US3222220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:05:20

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-23T15:09:59', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '32d249c6-f5c9-48f6-a903-2f5db12918d3' | System           | 23 Sep 2020 19:10:10 |
| User entered 'None (1)'  | System           | 23 Sep 2020 19:10:10 |

US3222220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:05:20

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-23T15:10:03', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '32d249c6-f5c9-48f6-a903-2f5db12918d3' | System           | 23 Sep 2020 19:10:10 |
| User entered '23 Sep 2020 15:10'   | System           | 23 Sep 2020 19:10:10 |

US3222220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:05:20

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| User entered '23 Sep 2020 12:00' | System           | 17 Sep 2020 13:47:37 |

US3222220

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:05:20

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| User entered '24 Sep 2020 11:59' | System           | 17 Sep 2020 13:47:37 |

US3222220

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:05:20

**TIMEPOINT**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| Data entry locked.   | System           | 17 Sep 2020 13:47:37 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System           | 17 Sep 2020 13:47:37 |

US3222220

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:05:20

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-17T10:15:58', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '154f56cc-fe23-45c3-af79-d10162007339' | System           | 17 Sep 2020 14:16:35 |
| User entered 'No interference with activity (1)'   | System           | 17 Sep 2020 14:16:35 |



US3222220

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:05:20

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-17T10:16:03', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '154f56cc-fe23-45c3-af79-d10162007339' | System           | 17 Sep 2020 14:16:35 |
| User entered 'No interference with activity (1)'   | System           | 17 Sep 2020 14:16:35 |

US3222220

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:05:20

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-17T10:16:07', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '154f56cc-fe23-45c3-af79-d10162007339' | System           | 17 Sep 2020 14:16:35 |
| User entered 'No interference with activity (1)'   | System           | 17 Sep 2020 14:16:35 |

US3222220

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:05:20

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-17T10:16:12', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '154f56cc-fe23-45c3-af79-d10162007339' | System           | 17 Sep 2020 14:16:35 |
| User entered 'No interference with activity (1)'   | System           | 17 Sep 2020 14:16:35 |

US3222220

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:05:20

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-17T10:16:17', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '154f56cc-fe23-45c3-af79-d10162007339' | System           | 17 Sep 2020 14:16:35 |
| User entered 'No interference with activity or 1-2 episodes/24 hours (1)'  | System           | 17 Sep 2020 14:16:35 |

US3222220

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:05:20

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-17T10:16:20', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '154f56cc-fe23-45c3-af79-d10162007339' | System           | 17 Sep 2020 14:16:35 |
| User entered 'No interference with activity (1)'   | System           | 17 Sep 2020 14:16:35 |

US3222220

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:05:20

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) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-17T10:16:25', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '154f56cc-fe23-45c3-af79-d10162007339' | System           | 17 Sep 2020 14:16:35 |
| User entered 'No (N)'  | System           | 17 Sep 2020 14:16:35 |

US3222220

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:05:20

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-17T10:16:29', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '154f56cc-fe23-45c3-af79-d10162007339' | System           | 17 Sep 2020 14:16:35 |
| User entered '17 Sep 2020 10:16'   | System           | 17 Sep 2020 14:16:35 |

US3222220

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:05:20

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| User entered '17 Sep 2020 09:52' | System           | 17 Sep 2020 13:47:37 |



US3222220

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:05:20

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| User entered '17 Sep 2020 12:22' | System           | 17 Sep 2020 13:47:37 |

US3222220

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:05:20

**TIMEPOINT**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| Data entry locked.                                | System           | 17 Sep 2020 13:47:37 |
| User entered 'Day 1, after vaccination (at home)' | System           | 17 Sep 2020 13:47:37 |

US3222220

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:05:20

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-17T20:39:23', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '8c2366ed-5613-4d9a-bd14-5939135632eb' | System           | 18 Sep 2020 00:39:33 |
| User entered 'None (0)'  | System           | 18 Sep 2020 00:39:33 |

US3222220

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:05:20

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-17T20:39:01', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '8c2366ed-5613-4d9a-bd14-5939135632eb' | System           | 18 Sep 2020 00:39:33 |
| User entered 'No interference with activity (1)'   | System           | 18 Sep 2020 00:39:33 |

US3222220

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:05:20

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-17T20:39:05', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '8c2366ed-5613-4d9a-bd14-5939135632eb' | System           | 18 Sep 2020 00:39:33 |
| User entered 'No interference with activity (1)'   | System           | 18 Sep 2020 00:39:33 |

US3222220

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:05:20

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-17T20:39:08', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '8c2366ed-5613-4d9a-bd14-5939135632eb' | System           | 18 Sep 2020 00:39:33 |
| User entered 'No interference with activity (1)'   | System           | 18 Sep 2020 00:39:33 |

US3222220

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:05:20

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-17T20:39:11', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '8c2366ed-5613-4d9a-bd14-5939135632eb' | System           | 18 Sep 2020 00:39:33 |
| User entered 'No interference with activity or 1-2 episodes/24 hours (1)'  | System           | 18 Sep 2020 00:39:33 |

US3222220

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:05:20

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-17T20:39:13', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '8c2366ed-5613-4d9a-bd14-5939135632eb' | System           | 18 Sep 2020 00:39:33 |
| User entered 'None (0)'  | System           | 18 Sep 2020 00:39:33 |



US3222220

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:05:20

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) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-17T20:39:17', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '8c2366ed-5613-4d9a-bd14-5939135632eb' | System           | 18 Sep 2020 00:39:33 |
| User entered 'No (N)'  | System           | 18 Sep 2020 00:39:33 |

US3222220

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:05:20

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-17T20:39:27', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '8c2366ed-5613-4d9a-bd14-5939135632eb' | System           | 18 Sep 2020 00:39:33 |
| User entered '17 Sep 2020 20:39'   | System           | 18 Sep 2020 00:39:33 |

US3222220

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:05:20

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| User entered '17 Sep 2020 13:17' | System           | 17 Sep 2020 13:47:37 |

US3222220

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:05:20

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| User entered '18 Sep 2020 11:59' | System           | 17 Sep 2020 13:47:37 |

US3222220

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:05:20

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| Data entry locked.   | System           | 17 Sep 2020 13:47:37 |
| User entered 'Day 2' | System           | 17 Sep 2020 13:47:37 |

US3222220

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:05:20

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-18T19:29:37', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '99601a89-cd11-4278-a6a3-317f36a33593' | System           | 18 Sep 2020 23:30:19 |
| User entered 'None (0)'  | System           | 18 Sep 2020 23:30:19 |

US3222220

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:05:20

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-18T19:29:43', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '99601a89-cd11-4278-a6a3-317f36a33593' | System           | 18 Sep 2020 23:30:19 |
| User entered 'No interference with activity (1)'   | System           | 18 Sep 2020 23:30:19 |

US3222220

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:05:20

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-18T19:29:48', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '99601a89-cd11-4278-a6a3-317f36a33593' | System           | 18 Sep 2020 23:30:19 |
| User entered 'No interference with activity (1)'   | System           | 18 Sep 2020 23:30:19 |



US3222220

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:05:20

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-18T19:29:53', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '99601a89-cd11-4278-a6a3-317f36a33593' | System           | 18 Sep 2020 23:30:19 |
| User entered 'No interference with activity (1)'   | System           | 18 Sep 2020 23:30:19 |

US3222220

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:05:20

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-18T19:29:59', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '99601a89-cd11-4278-a6a3-317f36a33593' | System           | 18 Sep 2020 23:30:19 |
| User entered 'No interference with activity or 1-2 episodes/24 hours (1)'  | System           | 18 Sep 2020 23:30:19 |

US3222220

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:05:20

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-18T19:30:03', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '99601a89-cd11-4278-a6a3-317f36a33593' | System           | 18 Sep 2020 23:30:19 |
| User entered 'No interference with activity (1)'   | System           | 18 Sep 2020 23:30:19 |

US3222220

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:05:20

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) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-18T19:30:09', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '99601a89-cd11-4278-a6a3-317f36a33593' | System           | 18 Sep 2020 23:30:19 |
| User entered 'No (N)'  | System           | 18 Sep 2020 23:30:19 |

US3222220

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:05:20

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-18T19:30:14', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '99601a89-cd11-4278-a6a3-317f36a33593' | System           | 18 Sep 2020 23:30:19 |
| User entered '18 Sep 2020 19:30'   | System           | 18 Sep 2020 23:30:19 |

US3222220

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:05:20

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| User entered '18 Sep 2020 12:00' | System           | 17 Sep 2020 13:47:37 |

US3222220

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:05:20

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| User entered '19 Sep 2020 11:59' | System           | 17 Sep 2020 13:47:37 |

US3222220

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:05:20

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| Data entry locked.   | System           | 17 Sep 2020 13:47:37 |
| User entered 'Day 3' | System           | 17 Sep 2020 13:47:37 |



US3222220

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:05:20

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-19T12:02:28', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '26f6553f-8f53-416a-babf-3aa91d6bc164' | System           | 19 Sep 2020 16:03:21 |
| User entered 'No interference with activity (1)'   | System           | 19 Sep 2020 16:03:21 |

US3222220

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:05:20

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-19T12:02:33', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '26f6553f-8f53-416a-babf-3aa91d6bc164' | System           | 19 Sep 2020 16:03:21 |
| User entered 'No interference with activity (1)'   | System           | 19 Sep 2020 16:03:21 |

US3222220

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:05:20

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-19T12:02:37', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '26f6553f-8f53-416a-babf-3aa91d6bc164' | System           | 19 Sep 2020 16:03:21 |
| User entered 'No interference with activity (1)'   | System           | 19 Sep 2020 16:03:21 |

US3222220

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:05:20

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-19T12:02:40', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '26f6553f-8f53-416a-babf-3aa91d6bc164' | System           | 19 Sep 2020 16:03:21 |
| User entered 'No interference with activity (1)'   | System           | 19 Sep 2020 16:03:21 |

US3222220

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:05:20

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-19T12:02:44', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '26f6553f-8f53-416a-babf-3aa91d6bc164' | System           | 19 Sep 2020 16:03:21 |
| User entered 'None (0)'  | System           | 19 Sep 2020 16:03:21 |

US3222220

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:05:20

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-19T12:02:46', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '26f6553f-8f53-416a-babf-3aa91d6bc164' | System           | 19 Sep 2020 16:03:21 |
| User entered 'None (0)'  | System           | 19 Sep 2020 16:03:21 |

US3222220

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:05:20

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) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-19T12:02:50', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '26f6553f-8f53-416a-babf-3aa91d6bc164' | System           | 19 Sep 2020 16:03:21 |
| User entered 'No (N)'  | System           | 19 Sep 2020 16:03:21 |

US3222220

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:05:20

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-19T12:02:54', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '26f6553f-8f53-416a-babf-3aa91d6bc164' | System           | 19 Sep 2020 16:03:21 |
| User entered '19 Sep 2020 12:02'   | System           | 19 Sep 2020 16:03:21 |



US3222220

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:05:20

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| User entered '19 Sep 2020 12:00' | System           | 17 Sep 2020 13:47:37 |

US3222220

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:05:20

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| User entered '20 Sep 2020 11:59' | System           | 17 Sep 2020 13:47:37 |

US3222220

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:05:20

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| Data entry locked.   | System           | 17 Sep 2020 13:47:37 |
| User entered 'Day 4' | System           | 17 Sep 2020 13:47:37 |

US3222220

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:05:20

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-20T12:03:27', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '9b698464-3fbb-4999-b9c9-9cc7ec8daf40' | System           | 20 Sep 2020 16:04:18 |
| User entered 'None (0)'  | System           | 20 Sep 2020 16:04:18 |

US3222220

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:05:20

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-20T12:03:32', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '9b698464-3fbb-4999-b9c9-9cc7ec8daf40' | System           | 20 Sep 2020 16:04:18 |
| User entered 'No interference with activity (1)'   | System           | 20 Sep 2020 16:04:18 |

US3222220

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:05:20

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-20T12:03:36', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '9b698464-3fbb-4999-b9c9-9cc7ec8daf40' | System           | 20 Sep 2020 16:04:18 |
| User entered 'No interference with activity (1)'   | System           | 20 Sep 2020 16:04:18 |

US3222220

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:05:20

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-20T12:03:39', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '9b698464-3fbb-4999-b9c9-9cc7ec8daf40' | System           | 20 Sep 2020 16:04:18 |
| User entered 'No interference with activity (1)'   | System           | 20 Sep 2020 16:04:18 |

US3222220

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:05:20

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-20T12:03:43', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '9b698464-3fbb-4999-b9c9-9cc7ec8daf40' | System           | 20 Sep 2020 16:04:18 |
| User entered 'None (0)'  | System           | 20 Sep 2020 16:04:18 |



US3222220

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:05:20

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-20T12:03:45', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '9b698464-3fbb-4999-b9c9-9cc7ec8daf40' | System           | 20 Sep 2020 16:04:18 |
| User entered 'None (0)'  | System           | 20 Sep 2020 16:04:18 |

US3222220

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:05:20

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) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-20T12:03:48', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '9b698464-3fbb-4999-b9c9-9cc7ec8daf40' | System           | 20 Sep 2020 16:04:18 |
| User entered 'No (N)'  | System           | 20 Sep 2020 16:04:18 |

US3222220

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:05:20

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-20T12:03:51', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '9b698464-3fbb-4999-b9c9-9cc7ec8daf40' | System           | 20 Sep 2020 16:04:18 |
| User entered '20 Sep 2020 12:03'   | System           | 20 Sep 2020 16:04:18 |

US3222220

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:05:20

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| User entered '20 Sep 2020 12:00' | System           | 17 Sep 2020 13:47:37 |

US3222220

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:05:20

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| User entered '21 Sep 2020 11:59' | System           | 17 Sep 2020 13:47:37 |

US3222220

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:05:20

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| Data entry locked.   | System           | 17 Sep 2020 13:47:37 |
| User entered 'Day 5' | System           | 17 Sep 2020 13:47:37 |

US3222220

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:05:20

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-21T12:05:39', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '5de3038e-852e-4d92-a3eb-85980b0ed88f' | System           | 21 Sep 2020 16:19:17 |
| User entered 'None (0)'  | System           | 21 Sep 2020 16:19:17 |

US3222220

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:05:20

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-21T12:05:44', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '5de3038e-852e-4d92-a3eb-85980b0ed88f' | System           | 21 Sep 2020 16:19:17 |
| User entered 'No interference with activity (1)'   | System           | 21 Sep 2020 16:19:17 |



US3222220

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:05:20

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-21T12:05:47', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '5de3038e-852e-4d92-a3eb-85980b0ed88f' | System           | 21 Sep 2020 16:19:17 |
| User entered 'None (0)'  | System           | 21 Sep 2020 16:19:17 |

US3222220

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:05:20

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-21T12:05:50', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '5de3038e-852e-4d92-a3eb-85980b0ed88f' | System           | 21 Sep 2020 16:19:17 |
| User entered 'None (0)'  | System           | 21 Sep 2020 16:19:17 |

US3222220

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:05:20

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-21T12:05:54', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '5de3038e-852e-4d92-a3eb-85980b0ed88f' | System           | 21 Sep 2020 16:19:17 |
| User entered 'None (0)'  | System           | 21 Sep 2020 16:19:17 |

US3222220

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:05:20

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-21T12:05:57', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '5de3038e-852e-4d92-a3eb-85980b0ed88f' | System           | 21 Sep 2020 16:19:17 |
| User entered 'None (0)'  | System           | 21 Sep 2020 16:19:17 |

US3222220

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:05:20

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) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-21T12:06:01', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '5de3038e-852e-4d92-a3eb-85980b0ed88f' | System           | 21 Sep 2020 16:19:17 |
| User entered 'No (N)'  | System           | 21 Sep 2020 16:19:17 |

US3222220

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:05:20

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-21T12:06:05', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: '5de3038e-852e-4d92-a3eb-85980b0ed88f' | System           | 21 Sep 2020 16:19:17 |
| User entered '21 Sep 2020 12:06'   | System           | 21 Sep 2020 16:19:17 |

US3222220

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:05:20

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| User entered '21 Sep 2020 12:00' | System           | 17 Sep 2020 13:47:37 |

US3222220

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:05:20

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| User entered '22 Sep 2020 11:59' | System           | 17 Sep 2020 13:47:37 |



US3222220

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:05:20

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| Data entry locked.   | System           | 17 Sep 2020 13:47:37 |
| User entered 'Day 6' | System           | 17 Sep 2020 13:47:37 |

US3222220

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:05:20

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-22T12:03:59', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: 'a3e6a069-5735-4c1b-97b0-e4f1c2097b92' | System           | 22 Sep 2020 16:05:10 |
| User entered 'None (0)'  | System           | 22 Sep 2020 16:05:10 |

US3222220

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:05:20

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-22T12:04:06', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: 'a3e6a069-5735-4c1b-97b0-e4f1c2097b92' | System           | 22 Sep 2020 16:05:10 |
| User entered 'No interference with activity (1)'   | System           | 22 Sep 2020 16:05:10 |

US3222220

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:05:20

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-22T12:04:09', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: 'a3e6a069-5735-4c1b-97b0-e4f1c2097b92' | System           | 22 Sep 2020 16:05:10 |
| User entered 'No interference with activity (1)'   | System           | 22 Sep 2020 16:05:10 |

US3222220

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:05:20

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-22T12:04:11', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: 'a3e6a069-5735-4c1b-97b0-e4f1c2097b92' | System           | 22 Sep 2020 16:05:10 |
| User entered 'No interference with activity (1)'   | System           | 22 Sep 2020 16:05:10 |

US3222220

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:05:20

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-22T12:04:13', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: 'a3e6a069-5735-4c1b-97b0-e4f1c2097b92' | System           | 22 Sep 2020 16:05:10 |
| User entered 'None (0)'  | System           | 22 Sep 2020 16:05:10 |

US3222220

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:05:20

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-22T12:04:16', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: 'a3e6a069-5735-4c1b-97b0-e4f1c2097b92' | System           | 22 Sep 2020 16:05:10 |
| User entered 'None (0)'  | System           | 22 Sep 2020 16:05:10 |

US3222220

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:05:20

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) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-22T12:04:19', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: 'a3e6a069-5735-4c1b-97b0-e4f1c2097b92' | System           | 22 Sep 2020 16:05:10 |
| User entered 'No (N)'  | System           | 22 Sep 2020 16:05:10 |



US3222220

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:05:20

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-22T12:04:22', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: 'a3e6a069-5735-4c1b-97b0-e4f1c2097b92' | System           | 22 Sep 2020 16:05:10 |
| User entered '22 Sep 2020 12:04'   | System           | 22 Sep 2020 16:05:10 |

US3222220

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:05:20

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| User entered '22 Sep 2020 12:00' | System           | 17 Sep 2020 13:47:37 |

US3222220

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:05:20

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| User entered '23 Sep 2020 11:59' | System           | 17 Sep 2020 13:47:37 |

US3222220

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:05:20

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| Data entry locked.   | System           | 17 Sep 2020 13:47:37 |
| User entered 'Day 7' | System           | 17 Sep 2020 13:47:37 |

US3222220

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:05:20

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-23T15:10:08', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: 'bdeac6b5-7b70-4343-b1c9-f1a746293554' | System           | 23 Sep 2020 19:10:29 |
| User entered 'None (0)'  | System           | 23 Sep 2020 19:10:29 |

US3222220

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:05:20

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-23T15:10:09', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: 'bdeac6b5-7b70-4343-b1c9-f1a746293554' | System           | 23 Sep 2020 19:10:29 |
| User entered 'None (0)'  | System           | 23 Sep 2020 19:10:29 |

US3222220

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:05:20

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-23T15:10:11', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: 'bdeac6b5-7b70-4343-b1c9-f1a746293554' | System           | 23 Sep 2020 19:10:29 |
| User entered 'None (0)'  | System           | 23 Sep 2020 19:10:29 |

US3222220

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:05:20

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-23T15:10:13', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: 'bdeac6b5-7b70-4343-b1c9-f1a746293554' | System           | 23 Sep 2020 19:10:29 |
| User entered 'None (0)'  | System           | 23 Sep 2020 19:10:29 |



US3222220

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:05:20

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-23T15:10:15', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: 'bdeac6b5-7b70-4343-b1c9-f1a746293554' | System           | 23 Sep 2020 19:10:29 |
| User entered 'None (0)'  | System           | 23 Sep 2020 19:10:29 |

US3222220

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:05:20

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-23T15:10:18', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: 'bdeac6b5-7b70-4343-b1c9-f1a746293554' | System           | 23 Sep 2020 19:10:29 |
| User entered 'None (0)'  | System           | 23 Sep 2020 19:10:29 |

US3222220

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:05:20

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) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-23T15:10:21', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: 'bdeac6b5-7b70-4343-b1c9-f1a746293554' | System           | 23 Sep 2020 19:10:29 |
| User entered 'No (N)'  | System           | 23 Sep 2020 19:10:29 |

US3222220

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:05:20

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-09-23T15:10:25', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: 'bdeac6b5-7b70-4343-b1c9-f1a746293554' | System           | 23 Sep 2020 19:10:29 |
| User entered '23 Sep 2020 15:10'   | System           | 23 Sep 2020 19:10:29 |

US3222220

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:05:20

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| User entered '23 Sep 2020 12:00' | System           | 17 Sep 2020 13:47:37 |

US3222220

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:05:20

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| User entered '24 Sep 2020 11:59' | System           | 17 Sep 2020 13:47:37 |

US3222220

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:20

[Was Contact Attempted?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 04 Apr 2021 18:17:07 |
| User signature succeeded. | Bruce Rankin (b) (4)  | 19 Feb 2021 22:18:05 |
| User entered 'Yes (Y)'    | Albert Garcia (b) (4) | 19 Oct 2020 17:24:30 |

US3222220

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:20

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

| Audit                      | User  | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                            | 04 Apr 2021 18:17:07 |
| User signature succeeded.  | Bruce Rankin (b) (4)                        | 19 Feb 2021 22:18:05 |
| User entered '24 Sep 2020' | (b) (4)<br>Albert Garcia (b) (4)<br>(b) (4) | 19 Oct 2020 17:24:30 |



US3222220

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:20

[Please select one status for the follow-up contact](#)

| Audit                                      | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)      | 04 Apr 2021 18:17:07 |
| User signature succeeded.                  | Bruce Rankin (b) (4)  | 19 Feb 2021 22:18:05 |
| User entered 'Contact Made (CONTACT MADE)' | Albert Garcia (b) (4) | 19 Oct 2020 17:24:30 |

US3222220

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:20

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 04 Apr 2021 18:17:07 |
| User signature succeeded. | Bruce Rankin (b) (4)             | 19 Feb 2021 22:18:05 |
| User entered empty.       | (b) (4)<br>Albert Garcia (b) (4) | 19 Oct 2020 17:24:30 |

US3222220

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:20

[Is the participant continuing to the next visit?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 04 Apr 2021 18:17:07 |
| User signature succeeded. | Bruce Rankin (b) (4)  | 19 Feb 2021 22:18:05 |
| User entered 'Yes (Y)'    | Albert Garcia (b) (4) | 19 Oct 2020 17:24:34 |

US3222220

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:20

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 18:17:07 |
| User entered 'I'  | System           | 19 Oct 2020 17:24:34 |

US3222220

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:20

[Was Contact Attempted?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 04 Apr 2021 18:17:07 |
| User signature succeeded. | Bruce Rankin (b) (4)  | 19 Feb 2021 22:18:05 |
| User entered 'Yes (Y)'    | Albert Garcia (b) (4) | 19 Oct 2020 17:25:13 |

US3222220

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:20

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

| Audit                     | User  | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                            | 04 Apr 2021 18:17:07 |
| User signature succeeded. | Bruce Rankin (b) (4)                        | 19 Feb 2021 22:18:05 |
| User entered '1 Oct 2020' | (b) (4)<br>Albert Garcia (b) (4)<br>(b) (4) | 19 Oct 2020 17:25:13 |

US3222220

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:20

[Please select one status for the follow-up contact](#)

| Audit                                      | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)      | 04 Apr 2021 18:17:07 |
| User signature succeeded.                  | Bruce Rankin (b) (4)  | 19 Feb 2021 22:18:05 |
| User entered 'Contact Made (CONTACT MADE)' | Albert Garcia (b) (4) | 19 Oct 2020 17:25:13 |

US3222220

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:20

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User  | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                            | 04 Apr 2021 18:17:07 |
| User signature succeeded. | Bruce Rankin (b) (4)                        | 19 Feb 2021 22:18:05 |
| User entered empty.       | (b) (4)<br>Albert Garcia (b) (4)<br>(b) (4) | 19 Oct 2020 17:25:13 |



US3222220

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:20

[Is the participant continuing to the next visit?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 04 Apr 2021 18:17:07 |
| User signature succeeded. | Bruce Rankin (b) (4)  | 19 Feb 2021 22:18:05 |
| User entered 'Yes (Y)'    | Albert Garcia (b) (4) | 19 Oct 2020 17:25:17 |

US3222220

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:20

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 18:17:07 |
| User entered 'I'  | System           | 19 Oct 2020 17:25:17 |

US3222220

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:20

[Was Contact Attempted?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 04 Apr 2021 18:17:07 |
| User signature succeeded. | Bruce Rankin (b) (4)  | 19 Feb 2021 22:18:05 |
| User entered 'Yes (Y)'    | Albert Garcia (b) (4) | 19 Oct 2020 17:25:32 |

US3222220

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:20

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

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 04 Apr 2021 18:17:07 |
| User signature succeeded. | Bruce Rankin (b) (4)             | 19 Feb 2021 22:18:05 |
| User entered '8 Oct 2020' | (b) (4)<br>Albert Garcia (b) (4) | 19 Oct 2020 17:25:32 |

US3222220

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:20

[Please select one status for the follow-up contact](#)

| Audit                                      | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)      | 04 Apr 2021 18:17:07 |
| User signature succeeded.                  | Bruce Rankin (b) (4)  | 19 Feb 2021 22:18:05 |
| User entered 'Contact Made (CONTACT MADE)' | Albert Garcia (b) (4) | 19 Oct 2020 17:25:32 |

US3222220

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:20

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 04 Apr 2021 18:17:07 |
| User signature succeeded. | Bruce Rankin (b) (4)             | 19 Feb 2021 22:18:05 |
| User entered empty.       | (b) (4)<br>Albert Garcia (b) (4) | 19 Oct 2020 17:25:32 |

US3222220

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:20

[Is the participant continuing to the next visit?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 04 Apr 2021 18:17:07 |
| User signature succeeded. | Bruce Rankin (b) (4)  | 19 Feb 2021 22:18:05 |
| User entered 'Yes (Y)'    | Albert Garcia (b) (4) | 19 Oct 2020 17:26:00 |

US3222220

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:20

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 18:17:07 |
| User entered 'I'  | System           | 19 Oct 2020 17:26:00 |



US3222220

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:05:20

[Was this visit performed?](#)

| Audit                     | User  | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                            | 04 Apr 2021 18:17:07 |
| User signature succeeded. | Bruce Rankin (b) (4)                        | 19 Feb 2021 22:18:05 |
| User entered 'Yes (Y)'    | (b) (4)<br>Alicia Cevera (b) (4)<br>(b) (4) | 20 Oct 2020 19:10:01 |

US3222220

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:05:20

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

| Audit                      | User  | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                            | 04 Apr 2021 18:17:07 |
| User signature succeeded.  | Bruce Rankin (b) (4)                        | 19 Feb 2021 22:18:05 |
| User entered '20 Oct 2020' | (b) (4)<br>Alicia Cevera (b) (4)<br>(b) (4) | 20 Oct 2020 19:10:01 |

US3222220

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:05:20

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

| Audit                          | User  | Time (GMT)           |
|--------------------------------|---|----------------------|
| Data hard locked.              | (b) (4), (b) (6)                            | 04 Apr 2021 18:17:07 |
| User signature succeeded.      | Bruce Rankin (b) (4)                        | 19 Feb 2021 22:18:05 |
| User entered 'Clinic (Clinic)' | (b) (4)<br>Alicia Cevera (b) (4)<br>(b) (4) | 20 Oct 2020 19:10:01 |

US3222220

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:05:20

[Folder OID](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 04 Apr 2021 18:17:07 |
| User entered 'VISIT3' | System           | 20 Oct 2020 19:10:01 |

US3222220

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:20

[Were vital signs assessed?](#)

| Audit                     | User  | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                            | 04 Apr 2021 18:17:07 |
| User signature succeeded. | Bruce Rankin (b) (4)                        | 19 Feb 2021 22:18:05 |
| User entered 'No (N)'     | (b) (4)<br>Alicia Cevera (b) (4)<br>(b) (4) | 20 Oct 2020 19:12:49 |

US3222220

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:20

Date of assessment (*dd MMM yyyy*)

| Audit                     | User  | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                            | 04 Apr 2021 18:17:07 |
| User signature succeeded. | Bruce Rankin (b) (4)                        | 19 Feb 2021 22:18:05 |
| User entered empty.       | (b) (4)<br>Alicia Cevera (b) (4)<br>(b) (4) | 20 Oct 2020 19:12:49 |

US3222220

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:20

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

| Audit                     | User  | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                            | 04 Apr 2021 18:17:07 |
| User signature succeeded. | Bruce Rankin (b) (4)                        | 19 Feb 2021 22:18:05 |
| User entered empty.       | (b) (4)<br>Alicia Cevera (b) (4)<br>(b) (4) | 20 Oct 2020 19:12:49 |

US3222220

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:20

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Apr 2021 18:17:07 |
| User entered empty. | System           | 20 Oct 2020 19:12:49 |



US3222220

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:20

Temperature (xxx.x)

| Audit                     | User  | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                            | 04 Apr 2021 18:17:07 |
| User signature succeeded. | Bruce Rankin (b) (4)                        | 19 Feb 2021 22:18:05 |
| User entered empty.       | (b) (4)<br>Alicia Cevera (b) (4)<br>(b) (4) | 20 Oct 2020 19:12:49 |

US3222220

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:20

[Route of measurement](#)

| Audit                     | User  | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                            | 04 Apr 2021 18:17:07 |
| User signature succeeded. | Bruce Rankin (b) (4)                        | 19 Feb 2021 22:18:05 |
| User entered empty.       | (b) (4)<br>Alicia Cevera (b) (4)<br>(b) (4) | 20 Oct 2020 19:12:49 |

US3222220

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:20

[If Other, specify](#)

| Audit                     | User  | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                            | 04 Apr 2021 18:17:07 |
| User signature succeeded. | Bruce Rankin (b) (4)                        | 19 Feb 2021 22:18:05 |
| User entered empty.       | (b) (4)<br>Alicia Cevera (b) (4)<br>(b) (4) | 20 Oct 2020 19:12:49 |

US3222220

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:20

[Pulse \(xxx\)](#)

| Audit                     | User  | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                            | 04 Apr 2021 18:17:07 |
| User signature succeeded. | Bruce Rankin (b) (4)                        | 19 Feb 2021 22:18:05 |
| User entered empty.       | (b) (4)<br>Alicia Cevera (b) (4)<br>(b) (4) | 20 Oct 2020 19:12:49 |

US3222220

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:20

[Pulse units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Apr 2021 18:17:07 |
| User entered empty. | System           | 20 Oct 2020 19:12:49 |

US3222220

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:20

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

| Audit                     | User  | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                            | 04 Apr 2021 18:17:07 |
| User signature succeeded. | Bruce Rankin (b) (4)                        | 19 Feb 2021 22:18:05 |
| User entered empty.       | (b) (4)<br>Alicia Cevera (b) (4)<br>(b) (4) | 20 Oct 2020 19:12:49 |

US3222220

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:20

[Respiratory Rate units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Apr 2021 18:17:07 |
| User entered empty. | System           | 20 Oct 2020 19:12:49 |

US3222220

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:20

Systolic Blood Pressure (xxx)

| Audit                     | User  | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                            | 04 Apr 2021 18:17:07 |
| User signature succeeded. | Bruce Rankin (b) (4)                        | 19 Feb 2021 22:18:05 |
| User entered empty.       | (b) (4)<br>Alicia Cevera (b) (4)<br>(b) (4) | 20 Oct 2020 19:12:49 |



US3222220

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:20

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Apr 2021 18:17:07 |
| User entered empty. | System           | 20 Oct 2020 19:12:49 |

US3222220

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:20

Diastolic Blood Pressure (xxx)

| Audit                     | User  | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                            | 04 Apr 2021 18:17:07 |
| User signature succeeded. | Bruce Rankin (b) (4)                        | 19 Feb 2021 22:18:05 |
| User entered empty.       | (b) (4)<br>Alicia Cevera (b) (4)<br>(b) (4) | 20 Oct 2020 19:12:49 |

US3222220

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:20

Diastolic Blood Pressure units

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Apr 2021 18:17:07 |
| User entered empty. | System           | 20 Oct 2020 19:12:49 |

US3222220

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:20

Height (derived)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 18:17:07 |
|                   |                  |                      |

US3222220

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:20

Weight (derived)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 18:17:07 |

US3222220

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:05:20

[Was the physical examination performed?](#)

| Audit                     | User  | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                            | 04 Apr 2021 18:17:07 |
| User signature succeeded. | Bruce Rankin (b) (4)                        | 19 Feb 2021 22:18:05 |
| User entered 'No (N)'     | (b) (4)<br>Alicia Cevera (b) (4)<br>(b) (4) | 20 Oct 2020 19:12:54 |

US3222220

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:05:20

Date of examination (dd MMM yyyy)

| Audit                     | User  | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                            | 04 Apr 2021 18:17:07 |
| User signature succeeded. | Bruce Rankin (b) (4)                        | 19 Feb 2021 22:18:05 |
| User entered empty.       | (b) (4)<br>Alicia Cevera (b) (4)<br>(b) (4) | 20 Oct 2020 19:12:54 |

US3222220

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:20

[Was the sample collected?](#)

| Audit                     | User  | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                            | 04 Apr 2021 18:17:07 |
| User signature succeeded. | Bruce Rankin (b) (4)                        | 19 Feb 2021 22:18:05 |
| User entered 'Yes (Y)'    | (b) (4)<br>Alicia Cevera (b) (4)<br>(b) (4) | 20 Oct 2020 19:13:08 |



US3222220

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:20

Collection date (*dd MMM yyyy*)

| Audit                      | User  | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                            | 04 Apr 2021 18:17:07 |
| User signature succeeded.  | Bruce Rankin (b) (4)                        | 19 Feb 2021 22:18:05 |
| User entered '20 Oct 2020' | (b) (4)<br>Alicia Cevera (b) (4)<br>(b) (4) | 20 Oct 2020 19:13:08 |

US3222220

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:20

Collection time (00:00-23:59)

| Audit                     | User  | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                            | 04 Apr 2021 18:17:07 |
| User signature succeeded. | Bruce Rankin (b) (4)                        | 19 Feb 2021 22:18:05 |
| User entered '13:55'      | (b) (4)<br>Alicia Cevera (b) (4)<br>(b) (4) | 20 Oct 2020 19:13:08 |

US3222220

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:20

Collection date and time (derived)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Apr 2021 18:17:07 |
| User entered '20 Oct 2020 13:55' | System           | 20 Oct 2020 19:13:08 |

US3222220

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:20

[Is the participant continuing to the next visit?](#)

| Audit                     | User  | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                            | 04 Apr 2021 18:17:07 |
| User signature succeeded. | Bruce Rankin (b) (4)                        | 19 Feb 2021 22:18:05 |
| User entered 'Yes (Y)'    | (b) (4)<br>Alicia Cevera (b) (4)<br>(b) (4) | 20 Oct 2020 19:13:14 |

US3222220

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:20

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 18:17:07 |
| User entered '1'  | System           | 20 Oct 2020 19:13:14 |

US3222220

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

**TIMEPOINT**

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 24 Apr 2021 02:38:42 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 22:54:56 |
| Data entry locked.                        | System           | 19 Aug 2020 17:32:54 |
| User entered 'Day 64'                     | System           | 19 Aug 2020 17:32:54 |

US3222220

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

[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) | 24 Apr 2021 02:38:42 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 22:54:56 |

US3222220

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

Have you been exposed to someone with 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) | 24 Apr 2021 02:38:42 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 22:54:56 |



**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Please 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)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 24 Apr 2021 02:38:42 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 22:54:56 |

US3222220

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

[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)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 24 Apr 2021 02:38:42 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 22:54:56 |

US3222220

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

Fever (Temperature  $\geq$  100.4°F/38°C)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 24 Apr 2021 02:38:42 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 22:54:56 |

US3222220

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

[Chills](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 24 Apr 2021 02:38:42 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 22:54:56 |

US3222220

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

[Cough](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 24 Apr 2021 02:38:42 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 22:54:56 |

US3222220

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

[Shortness of breath](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 24 Apr 2021 02:38:42 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 22:54:56 |

US3222220

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

[Difficulty breathing](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 24 Apr 2021 02:38:42 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 22:54:56 |

US3222220

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

[Fatigue](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 24 Apr 2021 02:38:42 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 22:54:56 |



US3222220

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

[Muscle aches](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 24 Apr 2021 02:38:42 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 22:54:56 |

US3222220

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

[Body aches](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 24 Apr 2021 02:38:42 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 22:54:56 |

US3222220

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

[Headache](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 24 Apr 2021 02:38:42 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 22:54:56 |

US3222220

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

[New loss of taste](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 24 Apr 2021 02:38:42 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 22:54:56 |

US3222220

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

[New loss of smell](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 24 Apr 2021 02:38:42 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 22:54:56 |

US3222220

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

[Sore throat](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 24 Apr 2021 02:38:42 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 22:54:56 |

US3222220

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

[Congestion](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 24 Apr 2021 02:38:42 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 22:54:56 |

US3222220

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

[Runny nose](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 24 Apr 2021 02:38:42 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 22:54:56 |



US3222220

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

[Nausea](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 24 Apr 2021 02:38:42 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 22:54:56 |

US3222220

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

[Vomiting](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 24 Apr 2021 02:38:42 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 22:54:56 |

US3222220

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

[Diarrhea](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 24 Apr 2021 02:38:42 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Please 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)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 24 Apr 2021 02:38:42 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 22:54:56 |

US3222220

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

[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)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 24 Apr 2021 02:38:42 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Please 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)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 24 Apr 2021 02:38:42 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Date and time of submission](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 24 Apr 2021 02:38:42 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 22:54:56 |

US3222220

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

[Patient Cloud Open Date & Time](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 24 Apr 2021 02:38:42 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 22:54:56 |
| Data entry locked.                        | System           | 19 Aug 2020 17:32:54 |
| User entered '19 Oct 2020 00:01'          | System           | 19 Aug 2020 17:32:54 |



US3222220

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

[Patient Cloud Close Date & Time](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 24 Apr 2021 02:38:42 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 22:54:56 |
| Data entry locked.                        | System           | 19 Aug 2020 17:32:54 |
| User entered '23 Oct 2020 23:59'          | System           | 19 Aug 2020 17:32:54 |

US3222220

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

**TIMEPOINT**

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| Data entry locked.    | System           | 19 Aug 2020 17:32:54 |
| User entered 'Day 71' | System           | 19 Aug 2020 17:32:54 |

US3222220

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

[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) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-10-26T21:42:52', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: 'b52342ee-0de3-47af-ac91-0dc3204e6f4d' | System           | 27 Oct 2020 01:43:12 |
| User entered 'No (N)'  | System           | 27 Oct 2020 01:43:12 |

US3222220

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

Have you been exposed to someone with 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) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-10-26T21:42:56', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: 'b52342ee-0de3-47af-ac91-0dc3204e6f4d' | System           | 27 Oct 2020 01:43:12 |
| User entered 'No (N)'  | System           | 27 Oct 2020 01:43:12 |

US3222220

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

[Date and time of submission](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a24e4005426bc86b)', Time: '2020-10-26T21:43:07', User OID: 'PatientReportedOutcome (US3222220)', ODM File OID: 'b52342ee-0de3-47af-ac91-0dc3204e6f4d' | System           | 27 Oct 2020 01:43:12 |
| User entered '26 Oct 2020 21:43:07'  | System           | 27 Oct 2020 01:43:12 |

US3222220

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

[Patient Cloud Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| Data entry locked.               | System           | 19 Aug 2020 17:32:54 |
| User entered '26 Oct 2020 00:01' | System           | 19 Aug 2020 17:32:54 |

US3222220

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

[Patient Cloud Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 01:44:16 |
| Data entry locked.               | System           | 19 Aug 2020 17:32:54 |
| User entered '30 Oct 2020 23:59' | System           | 19 Aug 2020 17:32:54 |

US3222220

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

**TIMEPOINT**

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 24 Apr 2021 02:38:42 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 22:54:56 |
| Data entry locked.                        | System           | 19 Aug 2020 17:32:54 |
| User entered 'Day 78'                     | System           | 19 Aug 2020 17:32:54 |



US3222220

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

[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) | 24 Apr 2021 02:38:42 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 22:54:56 |

US3222220

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

Have you been exposed to someone with 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) | 24 Apr 2021 02:38:42 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Please 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)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 24 Apr 2021 02:38:42 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 22:54:56 |

US3222220

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

[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)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 24 Apr 2021 02:38:42 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 22:54:56 |

US3222220

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

Fever (Temperature  $\geq$  100.4°F/38°C)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 24 Apr 2021 02:38:42 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 22:54:56 |

US3222220

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

[Chills](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 24 Apr 2021 02:38:42 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 22:54:56 |

US3222220

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

[Cough](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 24 Apr 2021 02:38:42 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 22:54:56 |

US3222220

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

[Shortness of breath](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 24 Apr 2021 02:38:42 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 22:54:56 |



US3222220

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

[Difficulty breathing](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 24 Apr 2021 02:38:42 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 22:54:56 |

US3222220

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

[Fatigue](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 24 Apr 2021 02:38:42 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 22:54:56 |

US3222220

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

[Muscle aches](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 24 Apr 2021 02:38:42 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 22:54:56 |

US3222220

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

[Body aches](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 24 Apr 2021 02:38:42 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 22:54:56 |

US3222220

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

[Headache](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 24 Apr 2021 02:38:42 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 22:54:56 |

US3222220

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

[New loss of taste](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 24 Apr 2021 02:38:42 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 22:54:56 |

US3222220

Folder: Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 16:05:20

[New loss of smell](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 24 Apr 2021 02:38:42 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 22:54:56 |

US3222220

Folder: Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 16:05:20

[Sore throat](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 24 Apr 2021 02:38:42 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 22:54:56 |



US3222220

Folder: Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 16:05:20

[Congestion](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 24 Apr 2021 02:38:42 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 22:54:56 |

US3222220

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

[Runny nose](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 24 Apr 2021 02:38:42 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 22:54:56 |

US3222220

Folder: Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 16:05:20

[Nausea](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 24 Apr 2021 02:38:42 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 22:54:56 |

US3222220

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

[Vomiting](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 24 Apr 2021 02:38:42 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 22:54:56 |

US3222220

Folder: Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 16:05:20

[Diarrhea](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 24 Apr 2021 02:38:42 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 22:54:56 |

US3222220

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

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**Generated On: 09 Jun 2021 16:05:20**

Please 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)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 24 Apr 2021 02:38:42 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 22:54:56 |

US3222220

Folder: Safety Follow Up Diary (1)

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[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)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 24 Apr 2021 02:38:42 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 22:54:56 |

**US3222220**

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

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| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 24 Apr 2021 02:38:42 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 22:54:56 |



**US3222220**

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[Date and time of submission](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 24 Apr 2021 02:38:42 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 22:54:56 |

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[Patient Cloud Open Date & Time](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 24 Apr 2021 02:38:42 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 22:54:56 |
| Data entry locked.                        | System           | 19 Aug 2020 17:32:54 |
| User entered '02 Nov 2020 00:01'          | System           | 19 Aug 2020 17:32:54 |

US3222220

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

[Patient Cloud Close Date & Time](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 24 Apr 2021 02:38:42 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 22:54:56 |
| Data entry locked.                        | System           | 19 Aug 2020 17:32:54 |
| User entered '06 Nov 2020 23:59'          | System           | 19 Aug 2020 17:32:54 |

US3222220

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

**TIMEPOINT**

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 24 Apr 2021 02:38:42 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 22:54:56 |
| Data entry locked.                        | System           | 19 Aug 2020 17:32:54 |
| User entered 'Day 92'                     | System           | 19 Aug 2020 17:32:54 |

US3222220

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

[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) | 24 Apr 2021 02:38:42 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 22:54:56 |

US3222220

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

Have you been exposed to someone with 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) | 24 Apr 2021 02:38:42 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 22:54:56 |

US3222220

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

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**Generated On: 09 Jun 2021 16:05:20**

Please 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)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 24 Apr 2021 02:38:42 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 22:54:56 |

US3222220

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

[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)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 24 Apr 2021 02:38:42 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 22:54:56 |



US3222220

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

Fever (Temperature  $\geq$  100.4°F/38°C)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 24 Apr 2021 02:38:42 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 22:54:56 |

US3222220

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

[Chills](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 24 Apr 2021 02:38:42 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 22:54:56 |

US3222220

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

[Cough](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 24 Apr 2021 02:38:42 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 22:54:56 |

US3222220

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

[Shortness of breath](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 24 Apr 2021 02:38:42 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 22:54:56 |

US3222220

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

[Difficulty breathing](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 24 Apr 2021 02:38:42 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 22:54:56 |

US3222220

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

[Fatigue](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 24 Apr 2021 02:38:42 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 22:54:56 |

US3222220

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

[Muscle aches](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 24 Apr 2021 02:38:42 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 22:54:56 |

US3222220

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

[Body aches](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 24 Apr 2021 02:38:42 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 22:54:56 |



US3222220

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

[Headache](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 24 Apr 2021 02:38:42 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 22:54:56 |

US3222220

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

[New loss of taste](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 24 Apr 2021 02:38:42 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 22:54:56 |

US3222220

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

[New loss of smell](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 24 Apr 2021 02:38:42 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 22:54:56 |

US3222220

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

[Sore throat](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 24 Apr 2021 02:38:42 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 22:54:56 |

US3222220

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

[Congestion](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 24 Apr 2021 02:38:42 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 22:54:56 |

US3222220

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

[Runny nose](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 24 Apr 2021 02:38:42 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 22:54:56 |

US3222220

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

[Nausea](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 24 Apr 2021 02:38:42 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 22:54:56 |

US3222220

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

[Vomiting](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 24 Apr 2021 02:38:42 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 22:54:56 |



US3222220

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

[Diarrhea](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 24 Apr 2021 02:38:42 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Please 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)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 24 Apr 2021 02:38:42 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 22:54:56 |

US3222220

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

[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)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 24 Apr 2021 02:38:42 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Please 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)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 24 Apr 2021 02:38:42 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Date and time of submission](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 24 Apr 2021 02:38:42 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 22:54:56 |

US3222220

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

[Patient Cloud Open Date & Time](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 24 Apr 2021 02:38:42 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 22:54:56 |
| Data entry locked.                        | System           | 19 Aug 2020 17:32:54 |
| User entered '16 Nov 2020 00:01'          | System           | 19 Aug 2020 17:32:54 |

US3222220

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:05:20

[Patient Cloud Close Date & Time](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 24 Apr 2021 02:38:42 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 22:54:56 |
| Data entry locked.                        | System           | 19 Aug 2020 17:32:54 |
| User entered '20 Nov 2020 23:59'          | System           | 19 Aug 2020 17:32:54 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|--|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered 'Day 96' | System | 19 Nov 2020 22:54:56 |



**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '20 Nov 2020 00:01' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '24 Nov 2020 23:59' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered 'Day 103' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '27 Nov 2020 00:01' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '01 Dec 2020 23:59' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered 'Day 110' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '04 Dec 2020 00:01' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '08 Dec 2020 23:59' | System | 19 Nov 2020 22:54:56 |



**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered 'Day 117' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '11 Dec 2020 00:01' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '15 Dec 2020 23:59' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered 'Day 124' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '18 Dec 2020 00:01' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '22 Dec 2020 23:59' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered 'Day 131' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '25 Dec 2020 00:01' | System | 19 Nov 2020 22:54:56 |



**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '29 Dec 2020 23:59' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered 'Day 138' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '01 Jan 2021 00:01' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '05 Jan 2021 23:59' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered 'Day 145' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '08 Jan 2021 00:01' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '12 Jan 2021 23:59' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered 'Day 152' | System | 19 Nov 2020 22:54:56 |



**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '15 Jan 2021 00:01' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '19 Jan 2021 23:59' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered 'Day 159' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '22 Jan 2021 00:01' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '26 Jan 2021 23:59' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered 'Day 166' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '29 Jan 2021 00:01' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '02 Feb 2021 23:59' | System | 19 Nov 2020 22:54:56 |



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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered 'Day 173' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '05 Feb 2021 00:01' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '09 Feb 2021 23:59' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered 'Day 180' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '12 Feb 2021 00:01' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '16 Feb 2021 23:59' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered 'Day 187' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '19 Feb 2021 00:01' | System | 19 Nov 2020 22:54:56 |



**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '23 Feb 2021 23:59' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered 'Day 194' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '26 Feb 2021 00:01' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '02 Mar 2021 23:59' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered 'Day 201' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '05 Mar 2021 00:01' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '09 Mar 2021 23:59' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered 'Day 208' | System | 19 Nov 2020 22:54:56 |



**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '12 Mar 2021 00:01' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '16 Mar 2021 23:59' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered 'Day 215' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '19 Mar 2021 00:01' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '23 Mar 2021 23:59' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered 'Day 222' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '26 Mar 2021 00:01' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '30 Mar 2021 23:59' | System | 19 Nov 2020 22:54:56 |



**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered 'Day 229' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '02 Apr 2021 00:01' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

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**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '06 Apr 2021 23:59' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered 'Day 236' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '09 Apr 2021 00:01' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '13 Apr 2021 23:59' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered 'Day 243' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '16 Apr 2021 00:01' | System | 19 Nov 2020 22:54:56 |



**US3222220**

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

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**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '20 Apr 2021 23:59' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered 'Day 250' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '23 Apr 2021 00:01' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '27 Apr 2021 23:59' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered 'Day 257' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '30 Apr 2021 00:01' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

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**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '04 May 2021 23:59' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered 'Day 264' | System | 19 Nov 2020 22:54:56 |



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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '07 May 2021 00:01' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '11 May 2021 23:59' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered 'Day 271' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '14 May 2021 00:01' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

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**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '18 May 2021 23:59' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered 'Day 278' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '21 May 2021 00:01' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '25 May 2021 23:59' | System | 19 Nov 2020 22:54:56 |



**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered 'Day 285' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '28 May 2021 00:01' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '01 Jun 2021 23:59' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered 'Day 292' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '04 Jun 2021 00:01' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

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**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '08 Jun 2021 23:59' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

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**Generated On: 09 Jun 2021 16:05:20**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered 'Day 299' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '11 Jun 2021 00:01' | System | 19 Nov 2020 22:54:56 |



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

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**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '15 Jun 2021 23:59' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

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**Generated On: 09 Jun 2021 16:05:20**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered 'Day 306' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '18 Jun 2021 00:01' | System | 19 Nov 2020 22:54:56 |

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

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**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '22 Jun 2021 23:59' | System | 19 Nov 2020 22:54:56 |

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

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**Generated On: 09 Jun 2021 16:05:20**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered 'Day 313' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '25 Jun 2021 00:01' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '29 Jun 2021 23:59' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered 'Day 320' | System | 19 Nov 2020 22:54:56 |



**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '02 Jul 2021 00:01' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '06 Jul 2021 23:59' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered 'Day 327' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '09 Jul 2021 00:01' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '13 Jul 2021 23:59' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered 'Day 334' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '16 Jul 2021 00:01' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '20 Jul 2021 23:59' | System | 19 Nov 2020 22:54:56 |



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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered 'Day 341' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '23 Jul 2021 00:01' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '27 Jul 2021 23:59' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered 'Day 348' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '30 Jul 2021 00:01' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '03 Aug 2021 23:59' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered 'Day 355' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '06 Aug 2021 00:01' | System | 19 Nov 2020 22:54:56 |



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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '10 Aug 2021 23:59' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered 'Day 362' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '13 Aug 2021 00:01' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '17 Aug 2021 23:59' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered 'Day 369' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '20 Aug 2021 00:01' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '24 Aug 2021 23:59' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered 'Day 376' | System | 19 Nov 2020 22:54:56 |



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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '27 Aug 2021 00:01' | System | 19 Nov 2020 22:54:56 |

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

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**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '31 Aug 2021 23:59' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered 'Day 383' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '03 Sep 2021 00:01' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

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**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '07 Sep 2021 23:59' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered 'Day 390' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '10 Sep 2021 00:01' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '14 Sep 2021 23:59' | System | 19 Nov 2020 22:54:56 |



**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered 'Day 397' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '17 Sep 2021 00:01' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '21 Sep 2021 23:59' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered 'Day 404' | System | 19 Nov 2020 22:54:56 |

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '24 Sep 2021 00:01' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '28 Sep 2021 23:59' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered 'Day 411' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '01 Oct 2021 00:01' | System | 19 Nov 2020 22:54:56 |



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

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[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '05 Oct 2021 23:59' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered 'Day 418' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '08 Oct 2021 00:01' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '12 Oct 2021 23:59' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered 'Day 425' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '15 Oct 2021 00:01' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '19 Oct 2021 23:59' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered 'Day 432' | System | 19 Nov 2020 22:54:56 |



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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '22 Oct 2021 00:01' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '26 Oct 2021 23:59' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered 'Day 439' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '29 Oct 2021 00:01' | System | 19 Nov 2020 22:54:56 |

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

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**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '02 Nov 2021 23:59' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

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**Generated On: 09 Jun 2021 16:05:20**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered 'Day 446' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '05 Nov 2021 00:01' | System | 19 Nov 2020 22:54:56 |

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

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[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '09 Nov 2021 23:59' | System | 19 Nov 2020 22:54:56 |



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

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**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered 'Day 453' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '12 Nov 2021 00:01' | System | 19 Nov 2020 22:54:56 |

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

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**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '16 Nov 2021 23:59' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered 'Day 460' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '19 Nov 2021 00:01' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '23 Nov 2021 23:59' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered 'Day 467' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '26 Nov 2021 00:01' | System | 19 Nov 2020 22:54:56 |



**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '30 Nov 2021 23:59' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered 'Day 474' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '03 Dec 2021 00:01' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '07 Dec 2021 23:59' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered 'Day 481' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '10 Dec 2021 00:01' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '14 Dec 2021 23:59' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered 'Day 488' | System | 19 Nov 2020 22:54:56 |



**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '17 Dec 2021 00:01' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '21 Dec 2021 23:59' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered 'Day 495' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '24 Dec 2021 00:01' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '28 Dec 2021 23:59' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered 'Day 502' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '31 Dec 2021 00:01' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '04 Jan 2022 23:59' | System | 19 Nov 2020 22:54:56 |



**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered 'Day 509' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '07 Jan 2022 00:01' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '11 Jan 2022 23:59' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered 'Day 516' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '14 Jan 2022 00:01' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

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**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '18 Jan 2022 23:59' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered 'Day 523' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '21 Jan 2022 00:01' | System | 19 Nov 2020 22:54:56 |



**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '25 Jan 2022 23:59' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered 'Day 530' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '28 Jan 2022 00:01' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '01 Feb 2022 23:59' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered 'Day 537' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '04 Feb 2022 00:01' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '08 Feb 2022 23:59' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered 'Day 544' | System | 19 Nov 2020 22:54:56 |



**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '11 Feb 2022 00:01' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '15 Feb 2022 23:59' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered 'Day 551' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '18 Feb 2022 00:01' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

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**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '22 Feb 2022 23:59' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered 'Day 558' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '25 Feb 2022 00:01' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '01 Mar 2022 23:59' | System | 19 Nov 2020 22:54:56 |



**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered 'Day 565' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '04 Mar 2022 00:01' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '08 Mar 2022 23:59' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered 'Day 572' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '11 Mar 2022 00:01' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

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**Generated On: 09 Jun 2021 16:05:20**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '15 Mar 2022 23:59' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

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**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered 'Day 579' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

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**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '18 Mar 2022 00:01' | System | 19 Nov 2020 22:54:56 |



**US3222220**

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

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '22 Mar 2022 23:59' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

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**Generated On: 09 Jun 2021 16:05:20**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered 'Day 586' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

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**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '25 Mar 2022 00:01' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

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**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '29 Mar 2022 23:59' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

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**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered 'Day 593' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

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**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '01 Apr 2022 00:01' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '05 Apr 2022 23:59' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

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**Generated On: 09 Jun 2021 16:05:20**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered 'Day 600' | System | 19 Nov 2020 22:54:56 |



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**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '08 Apr 2022 00:01' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '12 Apr 2022 23:59' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered 'Day 607' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '15 Apr 2022 00:01' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

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**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '19 Apr 2022 23:59' | System | 19 Nov 2020 22:54:56 |

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered 'Day 614' | System | 19 Nov 2020 22:54:56 |

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '22 Apr 2022 00:01' | System | 19 Nov 2020 22:54:56 |

**US3222220**

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

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**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '26 Apr 2022 23:59' | System | 19 Nov 2020 22:54:56 |



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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered 'Day 621' | System | 19 Nov 2020 22:54:56 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '29 Apr 2022 00:01' | System | 19 Nov 2020 22:54:56 |

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '03 May 2022 23:59' | System | 19 Nov 2020 22:54:56 |

**US3222220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered 'Day 628' | System | 19 Nov 2020 22:54:56 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '06 May 2022 00:01' | System | 19 Nov 2020 22:54:56 |

**US3222220**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '10 May 2022 23:59' | System | 19 Nov 2020 22:54:56 |

**US3222220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered 'Day 635' | System | 19 Nov 2020 22:54:56 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '13 May 2022 00:01' | System | 19 Nov 2020 22:54:56 |



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**Folder: New Safety Follow Up Diary (1)**

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[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '17 May 2022 23:59' | System | 19 Nov 2020 22:54:56 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered 'Day 642' | System | 19 Nov 2020 22:54:56 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '20 May 2022 00:01' | System | 19 Nov 2020 22:54:56 |

**US3222220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '24 May 2022 23:59' | System | 19 Nov 2020 22:54:56 |

**US3222220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered 'Day 649' | System | 19 Nov 2020 22:54:56 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '27 May 2022 00:01' | System | 19 Nov 2020 22:54:56 |

**US3222220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '31 May 2022 23:59' | System | 19 Nov 2020 22:54:56 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered 'Day 656' | System | 19 Nov 2020 22:54:56 |



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '03 Jun 2022 00:01' | System | 19 Nov 2020 22:54:56 |

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 16:05:20**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '07 Jun 2022 23:59' | System | 19 Nov 2020 22:54:56 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered 'Day 663' | System | 19 Nov 2020 22:54:56 |

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 16:05:20**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '10 Jun 2022 00:01' | System | 19 Nov 2020 22:54:56 |

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**Folder: New Safety Follow Up Diary (1)**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '14 Jun 2022 23:59' | System | 19 Nov 2020 22:54:56 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered 'Day 670' | System | 19 Nov 2020 22:54:56 |

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '17 Jun 2022 00:01' | System | 19 Nov 2020 22:54:56 |

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**Folder: New Safety Follow Up Diary (1)**

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[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '21 Jun 2022 23:59' | System | 19 Nov 2020 22:54:56 |



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered 'Day 677' | System | 19 Nov 2020 22:54:56 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '24 Jun 2022 00:01' | System | 19 Nov 2020 22:54:56 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '28 Jun 2022 23:59' | System | 19 Nov 2020 22:54:56 |

**US3222220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered 'Day 684' | System | 19 Nov 2020 22:54:56 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '01 Jul 2022 00:01' | System | 19 Nov 2020 22:54:56 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '05 Jul 2022 23:59' | System | 19 Nov 2020 22:54:56 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered 'Day 691' | System | 19 Nov 2020 22:54:56 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '08 Jul 2022 00:01' | System | 19 Nov 2020 22:54:56 |



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**Folder: New Safety Follow Up Diary (1)**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '12 Jul 2022 23:59' | System | 19 Nov 2020 22:54:56 |

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 16:05:20**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered 'Day 698' | System | 19 Nov 2020 22:54:56 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '15 Jul 2022 00:01' | System | 19 Nov 2020 22:54:56 |

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 16:05:20**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '19 Jul 2022 23:59' | System | 19 Nov 2020 22:54:56 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered 'Day 705' | System | 19 Nov 2020 22:54:56 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '22 Jul 2022 00:01' | System | 19 Nov 2020 22:54:56 |

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**Folder: New Safety Follow Up Diary (1)**

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[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '26 Jul 2022 23:59' | System | 19 Nov 2020 22:54:56 |

**US3222220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered 'Day 712' | System | 19 Nov 2020 22:54:56 |



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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '29 Jul 2022 00:01' | System | 19 Nov 2020 22:54:56 |

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**Folder: New Safety Follow Up Diary (1)**

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[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '02 Aug 2022 23:59' | System | 19 Nov 2020 22:54:56 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered 'Day 719' | System | 19 Nov 2020 22:54:56 |

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '05 Aug 2022 00:01' | System | 19 Nov 2020 22:54:56 |

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**Folder: New Safety Follow Up Diary (1)**

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[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '09 Aug 2022 23:59' | System | 19 Nov 2020 22:54:56 |

**US3222220**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 16:05:20**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered 'Day 726' | System | 19 Nov 2020 22:54:56 |

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '12 Aug 2022 00:01' | System | 19 Nov 2020 22:54:56 |

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**Folder: New Safety Follow Up Diary (1)**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '16 Aug 2022 23:59' | System | 19 Nov 2020 22:54:56 |



**US3222220**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 16:05:20**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered 'Day 733' | System | 19 Nov 2020 22:54:56 |

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '19 Aug 2022 00:01' | System | 19 Nov 2020 22:54:56 |

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**Folder: New Safety Follow Up Diary (1)**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '23 Aug 2022 23:59' | System | 19 Nov 2020 22:54:56 |

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 16:05:20**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered 'Day 740' | System | 19 Nov 2020 22:54:56 |

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '26 Aug 2022 00:01' | System | 19 Nov 2020 22:54:56 |

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**Folder: New Safety Follow Up Diary (1)**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '30 Aug 2022 23:59' | System | 19 Nov 2020 22:54:56 |

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 16:05:20**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered 'Day 747' | System | 19 Nov 2020 22:54:56 |

**US3222220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '02 Sep 2022 00:01' | System | 19 Nov 2020 22:54:56 |



**US3222220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '06 Sep 2022 23:59' | System | 19 Nov 2020 22:54:56 |

**US3222220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered 'Day 754' | System | 19 Nov 2020 22:54:56 |

**US3222220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '09 Sep 2022 00:01' | System | 19 Nov 2020 22:54:56 |

**US3222220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '13 Sep 2022 23:59' | System | 19 Nov 2020 22:54:56 |

**US3222220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered 'Day 761' | System | 19 Nov 2020 22:54:56 |

**US3222220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '16 Sep 2022 00:01' | System | 19 Nov 2020 22:54:56 |

**US3222220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '20 Sep 2022 23:59' | System | 19 Nov 2020 22:54:56 |

**US3222220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered 'Day 768' | System | 19 Nov 2020 22:54:56 |



**US3222220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '23 Sep 2022 00:01' | System | 19 Nov 2020 22:54:56 |

**US3222220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '27 Sep 2022 23:59' | System | 19 Nov 2020 22:54:56 |

**US3222220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered 'Day 775' | System | 19 Nov 2020 22:54:56 |

**US3222220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '30 Sep 2022 00:01' | System | 19 Nov 2020 22:54:56 |

**US3222220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '04 Oct 2022 23:59' | System | 19 Nov 2020 22:54:56 |

**US3222220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered 'Day 782' | System | 19 Nov 2020 22:54:56 |

**US3222220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '07 Oct 2022 00:01' | System | 19 Nov 2020 22:54:56 |

**US3222220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '11 Oct 2022 23:59' | System | 19 Nov 2020 22:54:56 |



**US3222220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered 'Day 789' | System | 19 Nov 2020 22:54:56 |

**US3222220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '14 Oct 2022 00:01' | System | 19 Nov 2020 22:54:56 |

**US3222220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '18 Oct 2022 23:59' | System | 19 Nov 2020 22:54:56 |

**US3222220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered 'Day 796' | System | 19 Nov 2020 22:54:56 |

**US3222220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '21 Oct 2022 00:01' | System | 19 Nov 2020 22:54:56 |

**US3222220**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:05:20**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 22:54:56 |
| Amendment Manager: User entered '25 Oct 2022 23:59' | System | 19 Nov 2020 22:54:56 |

US3222220

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:20

[Was Contact Attempted?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 04 Apr 2021 18:17:07 |
| User signature succeeded. | Bruce Rankin (b) (4)        | 19 Feb 2021 22:18:05 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 14 Nov 2020 15:01:53 |

US3222220

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:20

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 04 Apr 2021 18:17:07 |
| User signature succeeded.  | Bruce Rankin (b) (4)        | 19 Feb 2021 22:18:05 |
| User entered '10 Nov 2020' | (b) (4)<br>(b) (4), (b) (6) | 14 Nov 2020 15:01:53 |



US3222220

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:20

[Please select one status for the follow-up contact](#)

| Audit                                      | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)            | 04 Apr 2021 18:17:07 |
| User signature succeeded.                  | Bruce Rankin (b) (4)        | 19 Feb 2021 22:18:05 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4)<br>(b) (4), (b) (6) | 14 Nov 2020 15:01:53 |

US3222220

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:20

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 04 Apr 2021 18:17:07 |
| User signature succeeded. | Bruce Rankin (b) (4)        | 19 Feb 2021 22:18:05 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 14 Nov 2020 15:01:53 |

US3222220

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:20

[Is the participant continuing to the next visit?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 04 Apr 2021 18:17:07 |
| User signature succeeded. | Bruce Rankin (b) (4)        | 19 Feb 2021 22:18:05 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 14 Nov 2020 15:02:02 |

US3222220

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:20

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Apr 2021 18:17:07 |
| User entered 'I'  | System           | 14 Nov 2020 15:02:02 |

US3222220

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:20

[Was Contact Attempted?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 24 Apr 2021 10:48:40 |
| User signature succeeded. | Bruce Rankin (b) (4)        | 19 Feb 2021 22:18:05 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 15 Dec 2020 14:15:08 |

US3222220

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:20

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 24 Apr 2021 10:48:40 |
| User signature succeeded.  | Bruce Rankin (b) (4)        | 19 Feb 2021 22:18:05 |
| User entered '15 Dec 2020' | (b) (4)<br>(b) (4), (b) (6) | 15 Dec 2020 14:15:08 |

US3222220

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:20

[Please select one status for the follow-up contact](#)

| Audit                                      | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)            | 24 Apr 2021 10:48:40 |
| User signature succeeded.                  | Bruce Rankin (b) (4)        | 19 Feb 2021 22:18:05 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4)<br>(b) (4), (b) (6) | 15 Dec 2020 14:15:08 |

US3222220

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:20

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 24 Apr 2021 10:48:40 |
| User signature succeeded. | Bruce Rankin (b) (4)        | 19 Feb 2021 22:18:05 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 15 Dec 2020 14:15:08 |



US3222220

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:20

[Is the participant continuing to the next visit?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 24 Apr 2021 10:48:40 |
| User signature succeeded. | Bruce Rankin (b) (4)        | 19 Feb 2021 22:18:05 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 15 Dec 2020 14:18:27 |

US3222220

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:20

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 10:48:40 |
| User entered 'I'  | System           | 15 Dec 2020 14:18:27 |

US3222220

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:20

[Was Contact Attempted?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 24 Apr 2021 10:48:40 |
| User signature succeeded. | Bruce Rankin (b) (4)        | 19 Feb 2021 22:18:05 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 13 Jan 2021 19:22:23 |

US3222220

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:20

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 24 Apr 2021 10:48:40 |
| User signature succeeded.  | Bruce Rankin (b) (4)        | 19 Feb 2021 22:18:05 |
| User entered '12 Jan 2021' | (b) (4)<br>(b) (4), (b) (6) | 13 Jan 2021 19:22:23 |

US3222220

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:20

[Please select one status for the follow-up contact](#)

| Audit                                      | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)            | 24 Apr 2021 10:48:40 |
| User signature succeeded.                  | Bruce Rankin (b) (4)        | 19 Feb 2021 22:18:05 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4)<br>(b) (4), (b) (6) | 13 Jan 2021 19:22:23 |

US3222220

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:20

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 24 Apr 2021 10:48:40 |
| User signature succeeded. | Bruce Rankin (b) (4)        | 19 Feb 2021 22:18:05 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 13 Jan 2021 19:22:23 |

US3222220

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:20

[Is the participant continuing to the next visit?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 24 Apr 2021 10:48:40 |
| User signature succeeded. | Bruce Rankin (b) (4)        | 19 Feb 2021 22:18:05 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 13 Jan 2021 19:23:07 |

US3222220

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:20

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 10:48:40 |
| User entered 'I'  | System           | 13 Jan 2021 19:23:07 |



US3222220

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:20

[Was Contact Attempted?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 24 Apr 2021 10:48:40 |
| User signature succeeded. | Bruce Rankin (b) (4)        | 19 Feb 2021 22:18:05 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 15 Feb 2021 19:24:44 |

US3222220

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:20

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 24 Apr 2021 10:48:40 |
| User signature succeeded.  | Bruce Rankin (b) (4)        | 19 Feb 2021 22:18:05 |
| User entered '15 Feb 2021' | (b) (4)<br>(b) (4), (b) (6) | 15 Feb 2021 19:24:44 |

US3222220

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:20

[Please select one status for the follow-up contact](#)

| Audit                                      | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)            | 24 Apr 2021 10:48:40 |
| User signature succeeded.                  | Bruce Rankin (b) (4)        | 19 Feb 2021 22:18:05 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4)<br>(b) (4), (b) (6) | 15 Feb 2021 19:24:44 |

US3222220

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:20

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 24 Apr 2021 10:48:40 |
| User signature succeeded. | Bruce Rankin (b) (4)        | 19 Feb 2021 22:18:05 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 15 Feb 2021 19:24:44 |

US3222220

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:20

[Is the participant continuing to the next visit?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 24 Apr 2021 10:48:40 |
| User signature succeeded. | Bruce Rankin (b) (4)        | 19 Feb 2021 22:18:05 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 15 Feb 2021 19:28:28 |

US3222220

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:20

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 10:48:40 |
| User entered 'I'  | System           | 15 Feb 2021 19:28:28 |

US3222220

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:05:20

[Was this visit performed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4)        | 26 Apr 2021 13:56:59 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 07 Apr 2021 15:51:12 |

US3222220

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:05:20

Visit date (dd MMM yyyy)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| User signature succeeded.  | Bruce Rankin (b) (4)        | 26 Apr 2021 13:56:59 |
| User closed query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).   | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 11:55:25 |
| Query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' answered with '+8 days oow. recorded on protocol deviation form.' (Site from System). | (b) (4), (b) (6)            | 07 Apr 2021 18:36:21 |
| User opened query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).   | System                      | 07 Apr 2021 15:51:12 |
| User entered '7 Apr 2021'  | (b) (4), (b) (6)            | 07 Apr 2021 15:51:12 |



US3222220

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:05:20

Was visit performed at the participant's home or at the clinic?

| Audit                          | User                        | Time (GMT)           |
|--------------------------------|-----------------------------|----------------------|
| User signature succeeded.      | Bruce Rankin (b) (4)        | 26 Apr 2021 13:56:59 |
| User entered 'Clinic (Clinic)' | (b) (4)<br>(b) (4), (b) (6) | 07 Apr 2021 15:51:12 |

**US3222220**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:05:20**

[Folder OID](#)

| Audit                 | User   | Time (GMT)           |
|-----------------------|--------|----------------------|
| User entered 'VISIT4' | System | 07 Apr 2021 15:51:12 |

US3222220

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:20

[Were vital signs assessed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4)        | 26 Apr 2021 13:56:59 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 07 Apr 2021 18:36:29 |

US3222220

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:20

Date of assessment (*dd MMM yyyy*)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4)        | 26 Apr 2021 13:56:59 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 07 Apr 2021 18:36:29 |

US3222220

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:20

Time of assessment (00:00-23:59)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4)        | 26 Apr 2021 13:56:59 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 07 Apr 2021 18:36:29 |

**US3222220**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:05:20**

[Vital Signs Date and Time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 07 Apr 2021 18:36:29 |

US3222220

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:20

Temperature (xxx.x)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4)        | 26 Apr 2021 13:56:59 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 07 Apr 2021 18:36:29 |

US3222220

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:20

[Route of measurement](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4)        | 26 Apr 2021 13:56:59 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 07 Apr 2021 18:36:29 |



US3222220

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:20

[If Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4)        | 26 Apr 2021 13:56:59 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 07 Apr 2021 18:36:29 |

US3222220

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:20

[Pulse \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4)        | 26 Apr 2021 13:56:59 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 07 Apr 2021 18:36:29 |

**US3222220**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:05:20**

[Pulse units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 07 Apr 2021 18:36:29 |

US3222220

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:20

[Respiratory Rate \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4)        | 26 Apr 2021 13:56:59 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 07 Apr 2021 18:36:29 |

US3222220

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:20

[Respiratory Rate units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 07 Apr 2021 18:36:29 |

US3222220

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:20

Systolic Blood Pressure (xxx)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4)        | 26 Apr 2021 13:56:59 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 07 Apr 2021 18:36:29 |

US3222220

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:20

[Systolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 07 Apr 2021 18:36:29 |

US3222220

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:20

Diastolic Blood Pressure (xxx)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4)        | 26 Apr 2021 13:56:59 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 07 Apr 2021 18:36:29 |



US3222220

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:05:20

Diastolic Blood Pressure units

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 07 Apr 2021 18:36:29 |

US3222220

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:05:20

Was the physical examination performed?

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4)        | 26 Apr 2021 13:56:59 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 07 Apr 2021 18:36:33 |

US3222220

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:05:20

Date of examination (dd MMM yyyy)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4)        | 26 Apr 2021 13:56:59 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 07 Apr 2021 18:36:33 |

US3222220

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:20

[Was the sample collected?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4)        | 26 Apr 2021 13:56:59 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 07 Apr 2021 18:36:46 |

US3222220

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:20

Collection date (dd MMM yyyy)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4)        | 26 Apr 2021 13:56:59 |
| User entered '7 Apr 2021' | (b) (4)<br>(b) (4), (b) (6) | 07 Apr 2021 18:36:46 |

US3222220

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:20

Collection time (00:00-23:59)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4)        | 26 Apr 2021 13:56:59 |
| User entered '10:20'      | (b) (4)<br>(b) (4), (b) (6) | 07 Apr 2021 18:36:46 |

**US3222220**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:05:20**

[Collection date and time \(derived\)](#)

| Audit                           | User   | Time (GMT)           |
|---------------------------------|--------|----------------------|
| User entered '7 Apr 2021 10:20' | System | 07 Apr 2021 18:36:46 |

US3222220

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:20

[Is the participant continuing to the next visit?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4)        | 26 Apr 2021 13:56:59 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 07 Apr 2021 18:36:50 |



**US3222220**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:05:20**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 07 Apr 2021 18:36:50 |

US3222220

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:20

[Was Contact Attempted?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4)        | 26 Apr 2021 13:56:59 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 14 Apr 2021 12:36:49 |

US3222220

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:20

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | Bruce Rankin (b) (4)        | 26 Apr 2021 13:56:59 |
| User entered '14 Apr 2021' | (b) (4)<br>(b) (4), (b) (6) | 14 Apr 2021 12:36:49 |

US3222220

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:20

[Please select one status for the follow-up contact](#)

| Audit                                      | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| User signature succeeded.                  | Bruce Rankin (b) (4)        | 26 Apr 2021 13:56:59 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4)<br>(b) (4), (b) (6) | 14 Apr 2021 12:36:49 |

US3222220

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:05:20

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4)        | 26 Apr 2021 13:56:59 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 14 Apr 2021 12:36:49 |

US3222220

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:05:20

[Is the participant continuing to the next visit?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4)        | 26 Apr 2021 13:56:59 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 14 Apr 2021 12:36:58 |

**US3222220**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:05:20**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'I' | System | 14 Apr 2021 12:36:58 |

US3222220

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:05:20

[Was this visit performed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4)        | 26 Apr 2021 13:56:59 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 07 Apr 2021 15:50:03 |



US3222220

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:05:20

[Visit date \(dd MMM yyyy\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4)        | 26 Apr 2021 13:56:59 |
| User entered '7 Apr 2021' | (b) (4)<br>(b) (4), (b) (6) | 07 Apr 2021 15:50:03 |

US3222220

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:05:20

Was visit performed at the participant's home or at the clinic?

| Audit                          | User                        | Time (GMT)           |
|--------------------------------|-----------------------------|----------------------|
| User signature succeeded.      | Bruce Rankin (b) (4)        | 26 Apr 2021 13:56:59 |
| User entered 'Clinic (Clinic)' | (b) (4)<br>(b) (4), (b) (6) | 07 Apr 2021 15:50:03 |

**US3222220**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:05:20**

[Folder OID](#)

| Audit                        | User   | Time (GMT)           |
|------------------------------|--------|----------------------|
| User entered 'UNBLND_DECIDE' | System | 07 Apr 2021 15:50:03 |

US3222220

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:05:20

Date of updated informed consent (*dd MMM yyyy*)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4)        | 26 Apr 2021 13:56:59 |
| User entered '7 Apr 2021' | (b) (4)<br>(b) (4), (b) (6) | 07 Apr 2021 15:50:25 |

US3222220

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:05:20

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4)        | 26 Apr 2021 13:56:59 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 07 Apr 2021 15:50:25 |

US3222220

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:05:20

[Was the participant unblinded?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4)        | 26 Apr 2021 13:56:59 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 07 Apr 2021 15:50:25 |

US3222220

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 16:05:20**

[Under what version of the Protocol was the Participant unblinded?](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| User signature succeeded.                                  | Bruce Rankin (b) (4)        | 26 Apr 2021 13:56:59 |
| User entered 'Amendment 6 or later (Amendment 6 or later)' | (b) (4)<br>(b) (4), (b) (6) | 07 Apr 2021 15:50:25 |

US3222220

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:05:20

Date of unblinding (*dd MMM yyyy*)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4)        | 26 Apr 2021 13:56:59 |
| User entered '7 Apr 2021' | (b) (4)<br>(b) (4), (b) (6) | 07 Apr 2021 15:50:25 |



US3222220

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:05:20

[Participant randomization assignment](#)

| Audit                            | User                        | Time (GMT)           |
|----------------------------------|-----------------------------|----------------------|
| User signature succeeded.        | Bruce Rankin (b) (4)        | 26 Apr 2021 13:56:59 |
| User entered 'Placebo (Placebo)' | (b) (4)<br>(b) (4), (b) (6) | 07 Apr 2021 15:50:25 |

US3222220

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:05:20

[Actual Dose 1](#)

| Audit                            | User                        | Time (GMT)           |
|----------------------------------|-----------------------------|----------------------|
| User signature succeeded.        | Bruce Rankin (b) (4)        | 26 Apr 2021 13:56:59 |
| User entered 'Placebo (Placebo)' | (b) (4)<br>(b) (4), (b) (6) | 07 Apr 2021 15:50:25 |

US3222220

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:05:20

[Actual Dose 2](#)

| Audit                            | User                        | Time (GMT)           |
|----------------------------------|-----------------------------|----------------------|
| User signature succeeded.        | Bruce Rankin (b) (4)        | 26 Apr 2021 13:56:59 |
| User entered 'Placebo (Placebo)' | (b) (4)<br>(b) (4), (b) (6) | 07 Apr 2021 15:50:25 |

US3222220

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:05:20

[Will participant receive mRNA-1273?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4)        | 26 Apr 2021 13:56:59 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 07 Apr 2021 15:50:25 |

**US3222220**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 16:05:20**

[Placebo Only Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 07 Apr 2021 15:50:25 |

US3222220

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 16:05:20**

[Continuing with mRNA-1273](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 07 Apr 2021 15:50:25 |

US3222220

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:20

[Was the sample collected?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4)        | 26 Apr 2021 13:56:59 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 07 Apr 2021 15:50:41 |

US3222220

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:20

Collection date (*dd MMM yyyy*)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4)        | 26 Apr 2021 13:56:59 |
| User entered '7 Apr 2021' | (b) (4)<br>(b) (4), (b) (6) | 07 Apr 2021 15:50:41 |



US3222220

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:05:20

Collection time (00:00-23:59)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4)        | 26 Apr 2021 13:56:59 |
| User entered '10:20'      | (b) (4)<br>(b) (4), (b) (6) | 07 Apr 2021 15:50:41 |

**US3222220**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:05:20**

[Collection date and time \(derived\)](#)

| Audit                           | User   | Time (GMT)           |
|---------------------------------|--------|----------------------|
| User entered '7 Apr 2021 10:20' | System | 07 Apr 2021 15:50:41 |

US3222220

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:05:20

[Was the sample collected?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4)        | 26 Apr 2021 13:56:59 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 07 Apr 2021 15:50:57 |

US3222220

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:05:20

Collection date (*dd MMM yyyy*)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4)        | 26 Apr 2021 13:56:59 |
| User entered '7 Apr 2021' | (b) (4)<br>(b) (4), (b) (6) | 07 Apr 2021 15:50:57 |

US3222220

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:05:20

Collection time (00:00 - 23:59)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4)        | 26 Apr 2021 13:56:59 |
| User entered '10:23'      | (b) (4)<br>(b) (4), (b) (6) | 07 Apr 2021 15:50:57 |

**US3222220**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 16:05:20**

[Collection Date and Time \(derived\)](#)

| Audit                           | User   | Time (GMT)           |
|---------------------------------|--------|----------------------|
| User entered '7 Apr 2021 10:23' | System | 07 Apr 2021 15:50:57 |

US3222220

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 16:05:20

[Did the participant experience any adverse events?](#)

| Audit  | User  | Time (GMT)           |
|--|---|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                            | 03 May 2021 15:40:10 |
| User signature succeeded.  | Bruce Rankin (b) (4)                        | 28 Apr 2021 22:12:59 |
| User closed query 'Medical records in subject chart are for an ER visit 17Mar2021-18Mar2021 for alcohol intoxication. This is different than the current SAE for fall/temporal artery bleed. Please attempt to collect the medical records for the fall on/around 12Mar2021 and enter the alcohol intoxication ER visit as a separate AE since the subject visited the hospital.' (Site from CRA).   | (b) (4)<br>(b) (4), (b) (6)                 | 28 Apr 2021 15:41:04 |
| Query 'Medical records in subject chart are for an ER visit 17Mar2021-18Mar2021 for alcohol intoxication. This is different than the current SAE for fall/temporal artery bleed. Please attempt to collect the medical records for the fall on/around 12Mar2021 and enter the alcohol intoxication ER visit as a separate AE since the subject visited the hospital.' answered with 'CORRECT WHICH IS WHY WE RE-REQUESTED MEDICAL RECORDS FOR THE SAE.' (Site from CRA). | douglas winter (b) (4)<br>(b) (4)           | 26 Apr 2021 14:52:02 |
| User opened query 'Medical records in subject chart are for an ER visit 17Mar2021-18Mar2021 for alcohol intoxication. This is different than the current SAE for fall/temporal artery bleed. Please attempt to collect the medical records for the fall on/around 12Mar2021 and enter the alcohol intoxication ER visit as a separate AE since the subject visited the hospital.' (Site from CRA).   | (b) (4), (b) (6)                            | 21 Apr 2021 14:20:21 |
| DataPoint Verified.  | (b) (4), (b) (6)                            | 21 Apr 2021 14:09:27 |
| Signature has been broken.   | (b) (4), (b) (6)                            | 16 Mar 2021 13:18:10 |
| User entered 'Yes (Y)' reason for change: Data Entry Error   | (b) (4), (b) (6)                            | 16 Mar 2021 13:18:10 |
| User signature succeeded.  | Bruce Rankin (b) (4)                        | 19 Feb 2021 22:18:05 |
| User entered 'No (N)'  | (b) (4)<br>Amber Vasquez (b) (4)<br>(b) (4) | 19 Aug 2020 19:24:54 |

US3222220

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:20

[AEID](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Query 'Medical records appear to indicate that 18Mar2021 was the discharge date, please enter that on this page below.' canceled (Site from CRA). DataPoint Verified. | (b) (4), (b) (6) | 21 Apr 2021 14:16:05 |
|   |                  |                      |
|   | (b) (4), (b) (6) | 21 Apr 2021 14:12:09 |
|   |                  |                      |
| User opened query 'Medical records appear to indicate that 18Mar2021 was the discharge date, please enter that on this page below.' (Site from CRA).                  | (b) (4), (b) (6) | 21 Apr 2021 14:11:53 |
|   |                  |                      |
| Reviewed for Safety.  | (b) (4), (b) (6) | 17 Mar 2021 14:11:48 |
|   |                  |                      |
| User entered 'USA-US104-2021-mRNA-1273-P301000015'  | System           | 17 Mar 2021 14:11:45 |
| User entered 'New'  | (b) (4), (b) (6) | 17 Mar 2021 14:11:45 |
|   |                  |                      |



US3222220

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:20

[Adverse event](#)

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| User opened query 'Per MM: please provide more details regarding this SAE aetiology and also confirm severity assessment. ' (Site from DM).  | (b) (4), (b) (6)                | 26 Apr 2021 00:08:01 |
| DataPoint Verified.  | (b) (4), (b) (6)                | 21 Apr 2021 14:12:09 |
| User coded data point as SOC: Vascular disorders, HLGT: Vascular haemorrhagic disorders, HLT: Haemorrhages NEC, PT: Arterial haemorrhage, LLT: Arterial bleeding - version MedDRA\\23.0.   | Coder Import (b) (4)<br>(b) (4) | 15 Apr 2021 10:57:06 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.  | Coder Import (b) (4)<br>(b) (4) | 15 Apr 2021 10:57:06 |
| User closed query 'PV Query: The event term 'fall with temporal artery bleeding' contains multiple event terms. Please consider separating them into separate events.' (Site from Safety).   | (b) (4), (b) (6)                | 14 Apr 2021 14:59:11 |
| Data point term sent to Coder  | System                          | 13 Apr 2021 15:16:24 |
| Query 'PV Query: The event term 'fall with temporal artery bleeding' contains multiple event terms. Please consider separating them into separate events.' answered with 'will update ' (Site from Safety).  | Diana Toney (b) (4)<br>(b) (4)  | 13 Apr 2021 15:15:38 |
| User closed query 'CDM Coding, please split the term (FALL WITH TEMPORAL ARTERY BLEEDING) into two separate records, as 'FALL' and 'TEMPORAL ARTERY BLEEDING' reporting each term separately with all relevant information e.g. start and stop dates etc. ' (Site from System).                              | System                          | 13 Apr 2021 15:15:27 |
| Query 'CDM Coding, please split the term (FALL WITH TEMPORAL ARTERY BLEEDING) into two separate records, as 'FALL' and 'TEMPORAL ARTERY BLEEDING' reporting each term separately with all relevant information e.g. start and stop dates etc. ' answered with 'will make separate event' (Site from System). | Diana Toney (b) (4)<br>(b) (4)  | 13 Apr 2021 15:15:27 |
| Data point term sent to Coder  | System                          | 13 Apr 2021 15:15:21 |
| User entered 'TEMPORAL ARTERY BLEEDING' reason for change: Data Entry Error  | Diana Toney (b) (4)<br>(b) (4)  | 13 Apr 2021 15:14:46 |
| User opened query 'PV Query: The event term 'fall with temporal artery bleeding' contains multiple event terms. Please consider separating them into separate events.' (Site from Safety).   | (b) (4), (b) (6)                | 24 Mar 2021 12:57:41 |

US3222220

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:20

[Adverse event](#)

| Audit   | User                    | Time (GMT)           |
|---|-------------------------|----------------------|
| User opened query 'CDM Coding, please split the term (FALL WITH TEMPORAL ARTERY BLEEDING) into two separate records, as 'FALL' and 'TEMPORAL ARTERY BLEEDING' reporting each term separately with all relevant information e.g. start and stop dates etc. ' (Site from System). Data point term sent to Coder | Coder Import (b) (4)    | 18 Mar 2021 17:29:48 |
| User entered 'Fall with temporal artery bleeding'   | System (b) (4), (b) (6) | 16 Mar 2021 13:23:29 |
|   |                         | 16 Mar 2021 13:23:21 |

US3222220

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:20

[Was this a medically-attended AE?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6) | 21 Apr 2021 14:12:09 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 16 Mar 2021 13:23:21 |

US3222220

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:20

[Was this a Solicited Adverse Reaction?](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 21 Apr 2021 14:12:09 |
| User entered 'No (N)' | (b) (4), (b) (6) | 16 Mar 2021 13:23:21 |

US3222220

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:20

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 21 Apr 2021 14:12:09 |
| User entered 'No (N)' | (b) (4), (b) (6) | 16 Mar 2021 13:23:21 |

US3222220

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:20

Start date (dd MMM yyyy)

| Audit  | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| DataPoint Un-verified.   | douglas winter (b) (4) | 23 Apr 2021 20:49:29 |
|  | (b) (4)                |                      |
| User entered '11 Mar 2021' reason for change: Data Entry Error | douglas winter (b) (4) | 23 Apr 2021 20:49:29 |
|  | (b) (4)                |                      |
| DataPoint Verified.  | (b) (4), (b) (6)       | 21 Apr 2021 14:12:09 |
|  |                        |                      |
| User entered '12 Mar 2021'                                     | (b) (4), (b) (6)       | 16 Mar 2021 13:23:21 |
|  |                        |                      |

US3222220

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:20

Start time (00:00-23:59)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Apr 2021 14:12:09 |
| User entered empty. | (b) (4), (b) (6) | 16 Mar 2021 13:23:21 |

**US3222220**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:05:20**

[AE start date and time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 16 Mar 2021 13:23:21 |



US3222220

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:20

[Ongoing?](#)

| Audit   | User                              | Time (GMT)           |
|---|-----------------------------------|----------------------|
| User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System). | System                            | 23 Apr 2021 20:50:24 |
| User entered 'No (N)' reason for change: Data Entry Error   | douglas winter (b) (4)<br>(b) (4) | 23 Apr 2021 20:50:24 |
| User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System). | System                            | 23 Apr 2021 20:49:29 |
| DataPoint Un-verified.  | (b) (4), (b) (6)                  | 21 Apr 2021 14:16:35 |
| DataPoint Verified.   | (b) (4), (b) (6)                  | 21 Apr 2021 14:12:09 |
| User entered 'Yes (Y)'  | (b) (4), (b) (6)                  | 16 Mar 2021 13:23:21 |

US3222220

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:20

If not Ongoing, end date (dd MMM yyyy)

| Audit   | User                   | Time (GMT)           |
|---|------------------------|----------------------|
| User closed query 'PV Query: As the event, temporal artery bleeding, is considered resolve. Please provide a date the event resolved.' (Site from Safety).                    | (b) (4), (b) (6)       | 26 Apr 2021 17:52:10 |
| Query 'PV Query: As the event, temporal artery bleeding, is considered resolve. Please provide a date the event resolved.' answered with 'ADDED END DATE' (Site from Safety). | douglas winter (b) (4) | 23 Apr 2021 20:51:12 |
| User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).                    | System                 | 23 Apr 2021 20:49:29 |
| Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).        | System                 | 23 Apr 2021 20:49:29 |
| User entered '15 Mar 2021' reason for change: Data Entry Error  | douglas winter (b) (4) | 23 Apr 2021 20:49:29 |
| User opened query 'PV Query: As the event, temporal artery bleeding, is considered resolve. Please provide a date the event resolved.' (Site from Safety).                    | (b) (4), (b) (6)       | 22 Apr 2021 14:36:42 |
| DataPoint Un-verified.  | (b) (4), (b) (6)       | 21 Apr 2021 14:16:33 |
| DataPoint Verified.   | (b) (4), (b) (6)       | 21 Apr 2021 14:12:09 |
| User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).                    | System                 | 14 Apr 2021 18:36:54 |
| User entered empty.   | (b) (4), (b) (6)       | 16 Mar 2021 13:23:21 |

US3222220

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:20

End time (00:00-23:59)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available.' canceled (Site from Safety).    | (b) (4), (b) (6) | 03 May 2021 14:28:55 |
| DataPoint Verified.   | (b) (4), (b) (6) | 21 Apr 2021 14:12:09 |
| User opened query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available.' (Site from Safety). | (b) (4), (b) (6) | 24 Mar 2021 12:57:02 |
| User entered empty.   | (b) (4), (b) (6) | 16 Mar 2021 13:23:21 |

**US3222220**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:05:20**

[AE End Date and Time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 16 Mar 2021 13:23:21 |

US3222220

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:20

[Severity](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6) | 21 Apr 2021 14:12:09 |
| User closed query 'Data is required. Please complete.' (Site from System).             | System           | 06 Apr 2021 17:33:39 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System           | 06 Apr 2021 17:33:39 |
| User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error                   | (b) (4), (b) (6) | 06 Apr 2021 17:33:39 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System           | 16 Mar 2021 13:23:21 |
| User entered empty.  | (b) (4), (b) (6) | 16 Mar 2021 13:23:21 |

US3222220

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:20

[Is the adverse event serious?](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6) | 21 Apr 2021 14:12:09 |
| User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System). | System           | 16 Mar 2021 13:30:34 |
| User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System). | System           | 16 Mar 2021 13:23:21 |
| User entered 'Yes (Y)'   | (b) (4), (b) (6) | 16 Mar 2021 13:23:21 |

US3222220

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:20

[Death](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Apr 2021 14:12:09 |
| User entered '0'    | (b) (4), (b) (6) | 16 Mar 2021 13:23:21 |

US3222220

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:20

[Life threatening](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Apr 2021 14:12:09 |
| User entered '0'    | (b) (4), (b) (6) | 16 Mar 2021 13:23:21 |



US3222220

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:20

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit   | User                           | Time (GMT)           |
|---|--------------------------------|----------------------|
| DataPoint Un-verified.  | (b) (4), (b) (6)               | 21 Apr 2021 14:16:20 |
| DataPoint Verified.   | (b) (4), (b) (6)               | 21 Apr 2021 14:12:09 |
| User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).   | (b) (4), (b) (6)               | 15 Apr 2021 09:47:13 |
| Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'have not received records are still pending on knowing hospitalization status' (Site from System). | Diana Toney (b) (4)<br>(b) (4) | 13 Apr 2021 15:18:04 |
| User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).  |                                | 16 Mar 2021 13:30:34 |
| Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).  | System                         | 16 Mar 2021 13:30:34 |
| User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).   | System                         | 16 Mar 2021 13:30:34 |
| User entered '1' reason for change: Data Entry Error  | (b) (4), (b) (6)               | 16 Mar 2021 13:30:34 |
| User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).  | System                         | 16 Mar 2021 13:23:21 |
| User entered '0'  | (b) (4), (b) (6)               | 16 Mar 2021 13:23:21 |

US3222220

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:20

Hospital Admission Date (*dd MMM yyyy*)

| Audit  | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| User entered '11 Mar 2021' reason for change: Data Entry Error | douglas winter (b) (4) | 23 Apr 2021 20:52:14 |
| DataPoint Un-verified.   | (b) (4)                |                      |
|  | (b) (4), (b) (6)       | 21 Apr 2021 14:16:17 |
| DataPoint Verified.  | (b) (4), (b) (6)       | 21 Apr 2021 14:12:09 |
| User entered '12 Mar 2021'                                     | (b) (4), (b) (6)       | 16 Mar 2021 13:23:21 |

US3222220

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:20

Hospital Discharge Date (dd MMM yyyy)

| Audit  | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).                                   | (b) (4), (b) (6)       | 26 Apr 2021 17:52:16 |
| Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'ADDED HOSPITAL DISCHARGE DATE' (Site from Safety). | douglas winter (b) (4) | 23 Apr 2021 20:52:33 |
| User entered '15 Mar 2021' reason for change: Data Entry Error   | (b) (4)                | 23 Apr 2021 20:52:14 |
| DataPoint Un-verified.   | (b) (4), (b) (6)       | 21 Apr 2021 14:12:16 |
| DataPoint Verified.  | (b) (4), (b) (6)       | 21 Apr 2021 14:12:09 |
| User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).                                   | (b) (4), (b) (6)       | 24 Mar 2021 12:56:42 |
| User entered empty.  | (b) (4), (b) (6)       | 16 Mar 2021 13:23:21 |

US3222220

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:20

[Admitted to ICU?](#)

| Audit   | User                   | Time (GMT)           |
|---|------------------------|----------------------|
| User closed query 'Per CDM: Response noted. Please update data once available' (Site from DM).  | (b) (4), (b) (6)       | 27 Apr 2021 15:16:18 |
| Query 'Per CDM: Response noted. Please update data once available' answered with 'ADDED NO' (Site from DM).   | douglas winter (b) (4) | 23 Apr 2021 20:52:41 |
| DataPoint Un-verified.  | (b) (4)                |                      |
|   | douglas winter (b) (4) | 23 Apr 2021 20:52:14 |
| User entered 'No (N)' reason for change: Data Entry Error   | (b) (4)                |                      |
| DataPoint Verified.   | douglas winter (b) (4) | 23 Apr 2021 20:52:14 |
|   | (b) (4)                |                      |
|   | (b) (4), (b) (6)       | 21 Apr 2021 14:12:09 |
|   | (b) (4), (b) (6)       |                      |
| User opened query 'Per CDM: Response noted. Please update data once available' (Site from DM).  | (b) (4), (b) (6)       | 15 Apr 2021 09:46:55 |
| User closed query 'Per CDM: Please verify that Requires inpatient or prolongation of existing Hospitalization is checked however Admitted to ICU? should be YES or NO. Please review and updated accordingly. Else clarify.' (Site from DM).                        | (b) (4), (b) (6)       | 15 Apr 2021 09:46:55 |
| Query 'Per CDM: Please verify that Requires inpatient or prolongation of existing Hospitalization is checked however Admitted to ICU? should be YES or NO. Please review and updated accordingly. Else clarify.' answered with 'waiting on records' (Site from DM). | Diana Toney (b) (4)    | 13 Apr 2021 15:18:22 |
|   | (b) (4)                |                      |
| User opened query 'Per CDM: Please verify that Requires inpatient or prolongation of existing Hospitalization is checked however Admitted to ICU? should be YES or NO. Please review and updated accordingly. Else clarify.' (Site from DM).                        | (b) (4), (b) (6)       | 25 Mar 2021 15:36:06 |
| User entered empty.   | (b) (4), (b) (6)       | 16 Mar 2021 13:23:21 |

US3222220

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:20

[Number of Days in ICU](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Apr 2021 14:12:09 |
| User entered empty. | (b) (4), (b) (6) | 16 Mar 2021 13:23:21 |

US3222220

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:20

[Persistent or significant disability or incapacity](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Apr 2021 14:12:09 |
| User entered '0'    | (b) (4), (b) (6) | 16 Mar 2021 13:23:21 |

US3222220

Folder: Adverse Events

Form: Adverse Events (1)

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[Congenital anomaly or birth defect](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Apr 2021 14:12:09 |
| User entered '0'    | (b) (4), (b) (6) | 16 Mar 2021 13:23:21 |

US3222220

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:20

[Other medically important event](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Apr 2021 14:12:09 |
| User entered '0'    | (b) (4), (b) (6) | 16 Mar 2021 13:23:21 |



US3222220

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:20

[Relationship to investigational product](#)

| Audit  | User                           | Time (GMT)           |
|--|--------------------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6)               | 21 Apr 2021 14:12:09 |
| User closed query 'PV Query: Since the subject received two doses of study drug before this event started, please consider updating the relationship to investigational product as "Related" or "Not Related". Please update the CRF accordingly.' (Site from Safety).             | (b) (4), (b) (6)               | 14 Apr 2021 14:59:17 |
| Query 'PV Query: Since the subject received two doses of study drug before this event started, please consider updating the relationship to investigational product as "Related" or "Not Related". Please update the CRF accordingly.' answered with 'updated' (Site from Safety). | Diana Toney (b) (4)<br>(b) (4) | 13 Apr 2021 15:19:02 |
| User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error   | Diana Toney (b) (4)<br>(b) (4) | 13 Apr 2021 15:18:43 |
| User opened query 'PV Query: Since the subject received two doses of study drug before this event started, please consider updating the relationship to investigational product as "Related" or "Not Related". Please update the CRF accordingly.' (Site from Safety).             | (b) (4), (b) (6)               | 24 Mar 2021 12:56:07 |
| User entered 'Not Applicable (NOT APPLICABLE)'   | (b) (4), (b) (6)               | 16 Mar 2021 13:23:21 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:20

[Relationship to Study Procedure](#)

| Audit                                    | User             | Time (GMT)           |
|--|------------------|----------------------|
| DataPoint Verified.                      | (b) (4), (b) (6) | 21 Apr 2021 14:12:09 |
| User entered 'Not Related (NOT RELATED)' | (b) (4), (b) (6) | 16 Mar 2021 13:23:21 |

US3222220

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:20

Action taken with investigational product

| Audit  | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| User closed query 'Please update action taken for the event temporal artery bleeding from none to not applicable.' (Site from Safety).   | (b) (4), (b) (6)       | 26 Apr 2021 17:52:20 |
| Query 'Please update action taken for the event temporal artery bleeding from none to not applicable.' answered with 'UPDATED ' (Site from Safety).  | douglas winter (b) (4) | 23 Apr 2021 20:53:40 |
| DataPoint Un-verified.   | (b) (4)                |                      |
| User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error   | douglas winter (b) (4) | 23 Apr 2021 20:53:05 |
| User opened query 'Please update action taken for the event temporal artery bleeding from none to not applicable.' (Site from Safety).   | (b) (4)                |                      |
| DataPoint Verified.  | (b) (4), (b) (6)       | 22 Apr 2021 14:35:58 |
| User closed query 'PV Query: As the last dose of study drug was given on 17 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).                                     | (b) (4), (b) (6)       | 21 Apr 2021 14:12:09 |
| Query 'PV Query: As the last dose of study drug was given on 17 Sep 2020, please update the action taken with study drug from none to not applicable.' answered with 'updated on AE to not applicable' (Site from Safety). | (b) (4), (b) (6)       | 14 Apr 2021 14:59:19 |
| User opened query 'PV Query: As the last dose of study drug was given on 17 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).                                     | Diana Toney (b) (4)    | 13 Apr 2021 15:20:09 |
| User entered 'None (NONE)'   | (b) (4)                |                      |
|  | (b) (4), (b) (6)       | 24 Mar 2021 12:55:33 |
|  | (b) (4), (b) (6)       | 16 Mar 2021 13:23:21 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:20

[None](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Apr 2021 14:12:09 |
| User entered '0'    | (b) (4), (b) (6) | 16 Mar 2021 13:23:21 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:20

[Concomitant Medication](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6) | 21 Apr 2021 14:12:09 |
| User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).<br>User entered 'I' | (b) (4), (b) (6) | 05 Apr 2021 12:34:27 |
|  | (b) (4), (b) (6) | 16 Mar 2021 13:23:21 |

US3222220

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:20

[Concomitant Procedure](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Apr 2021 14:12:09 |
| User entered '0'    | (b) (4), (b) (6) | 16 Mar 2021 13:23:21 |

US3222220

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:20

[Outcome](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6) | 21 Apr 2021 14:12:09 |
| User closed query 'PV Query: Please provide the final event outcome as it was missing in the source document. Please update EDC accordingly.' (Site from Safety).             | (b) (4), (b) (6) | 15 Apr 2021 13:29:15 |
| Query 'PV Query: Please provide the final event outcome as it was missing in the source document. Please update EDC accordingly.' answered with 'updated' (Site from Safety). | (b) (4), (b) (6) | 14 Apr 2021 18:37:26 |
| User closed query 'Data is required. Please complete.' (Site from System).  | System           | 14 Apr 2021 18:36:54 |
| Query 'Data is required. Please complete.' answered by data change (Site from System).  | System           | 14 Apr 2021 18:36:54 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error  | (b) (4), (b) (6) | 14 Apr 2021 18:36:54 |
| User opened query 'PV Query: Please provide the final event outcome as it was missing in the source document. Please update EDC accordingly.' (Site from Safety).             | (b) (4), (b) (6) | 24 Mar 2021 12:58:41 |
| User opened query 'Data is required. Please complete.' (Site from System).  | System           | 16 Mar 2021 13:23:21 |
| User entered empty.   | (b) (4), (b) (6) | 16 Mar 2021 13:23:21 |

US3222220

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:20

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Apr 2021 14:12:09 |
| User entered empty. | (b) (4), (b) (6) | 16 Mar 2021 13:23:21 |



US3222220

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:20

[Narrative](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Query 'PV Query: What was the reason for the fall? (i.e. mechanical, accidental, underlying condition, etc)' canceled (Site from Safety).  | (b) (4), (b) (6) | 03 May 2021 14:32:39 |
| DataPoint Verified.  | (b) (4), (b) (6) | 21 Apr 2021 14:12:09 |
| User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).                                       | (b) (4), (b) (6) | 24 Mar 2021 12:59:07 |
| User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).                    | (b) (4), (b) (6) | 24 Mar 2021 12:58:54 |
| User opened query 'PV Query: Did the subject have any medical history of bleeding disorder? Was the SAE considered a worsening of the subject's medical history?' (Site from Safety).  | (b) (4), (b) (6) | 24 Mar 2021 12:58:27 |
| 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) | 24 Mar 2021 12:58:11 |
| User opened query 'PV Query: What was the reason for the fall? (i.e. mechanical, accidental, underlying condition, etc)' (Site from Safety).   | (b) (4), (b) (6) | 24 Mar 2021 12:57:56 |
| User opened query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).   | (b) (4), (b) (6) | 24 Mar 2021 12:57:18 |

US3222220

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:20

[Narrative](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| 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) | 24 Mar 2021 12:56:27 |
| User entered 'SAE hospitalized 12 Mar 2021'  | (b) (4), (b) (6) | 16 Mar 2021 13:23:21 |

US3222220

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:05:20

Serious Adverse Event Derived (CSA Programming Field Only)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'I' | System | 16 Mar 2021 13:23:21 |

**US3222220**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:05:20**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'I' | System | 16 Mar 2021 13:23:21 |

**US3222220**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:05:20**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '0' | System | 23 Apr 2021 20:52:14 |

US3222220

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:20

[AEID](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Query 'Medical records appear to indicate that 18Mar2021 was the discharge date, please enter that on this page below.' canceled (Site from CRA).    | (b) (4), (b) (6) | 21 Apr 2021 14:13:19 |
| User opened query 'Medical records appear to indicate that 18Mar2021 was the discharge date, please enter that on this page below.' (Site from CRA). | (b) (4), (b) (6) | 21 Apr 2021 14:12:59 |
| DataPoint Verified.  | (b) (4), (b) (6) | 21 Apr 2021 14:12:09 |
| Reviewed for Safety.   | (b) (4), (b) (6) | 14 Apr 2021 13:21:23 |
| User entered<br>'USA-US104-2021-mRNA-1273-P301000015'  | (b) (4), (b) (6) | 14 Apr 2021 13:21:16 |

US3222220

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:20

[Adverse event](#)

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6)                | 21 Apr 2021 14:12:09 |
| User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Non-site specific injuries NEC, PT: Fall, LLT: Fall - version MedDRA\\23.0. | Coder Import (b) (4)<br>(b) (4) | 13 Apr 2021 16:39:15 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.   | Coder Import (b) (4)<br>(b) (4) | 13 Apr 2021 16:39:15 |
| Data point term sent to Coder  | System                          | 13 Apr 2021 15:25:33 |
| User entered 'Fall'  | Diana Toney (b) (4)<br>(b) (4)  | 13 Apr 2021 15:24:43 |

US3222220

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:20

[Was this a medically-attended AE?](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)               | 21 Apr 2021 14:12:09 |
| User entered 'Yes (Y)' | Diana Toney (b) (4)<br>(b) (4) | 13 Apr 2021 15:24:43 |



US3222220

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:20

[Was this a Solicited Adverse Reaction?](#)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)               | 21 Apr 2021 14:12:09 |
| User entered 'No (N)' | Diana Toney (b) (4)<br>(b) (4) | 13 Apr 2021 15:24:43 |

US3222220

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:20

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit                 | User                           | Time (GMT)           |
|-----------------------|--------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)               | 21 Apr 2021 14:12:09 |
| User entered 'No (N)' | Diana Toney (b) (4)<br>(b) (4) | 13 Apr 2021 15:24:43 |

US3222220

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:20

Start date (dd MMM yyyy)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)               | 21 Apr 2021 14:12:09 |
| User entered '12 Mar 2021' | Diana Toney (b) (4)<br>(b) (4) | 13 Apr 2021 15:24:43 |

US3222220

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:20

Start time (00:00-23:59)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 21 Apr 2021 14:12:09 |
| User entered empty. | Diana Toney (b) (4)<br>(b) (4) | 13 Apr 2021 15:24:43 |

**US3222220**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:05:20**

[AE start date and time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 13 Apr 2021 15:24:43 |

US3222220

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:20

[Ongoing?](#)

| Audit  | User                                 | Time (GMT)           |
|--|--------------------------------------|----------------------|
| User opened query 'Per MM: please provide final outcome and end date when available. ' (Site from DM).<br>DataPoint Un-verified. | (b) (4), (b) (6)<br>(b) (4), (b) (6) | 26 Apr 2021 00:08:29 |
| DataPoint Verified.  | (b) (4), (b) (6)<br>(b) (4), (b) (6) | 21 Apr 2021 14:17:21 |
| User entered 'Yes (Y)'   | Diana Toney (b) (4)<br>(b) (4)       | 21 Apr 2021 14:12:09 |
|  |                                      | 13 Apr 2021 15:24:43 |

US3222220

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:20

If not Ongoing, end date (dd MMM yyyy)

| Audit   | User                           | Time (GMT)           |
|---|--------------------------------|----------------------|
| User opened query 'PV Query: Please provide the event end date for the event, fall, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available.' (Site from Safety). | (b) (4), (b) (6)               | 03 May 2021 14:28:30 |
| DataPoint Un-verified.  | (b) (4), (b) (6)               | 21 Apr 2021 14:17:22 |
| DataPoint Verified.   | (b) (4), (b) (6)               | 21 Apr 2021 14:12:09 |
| User entered empty.   | Diana Toney (b) (4)<br>(b) (4) | 13 Apr 2021 15:24:43 |

US3222220

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:20

End time (00:00-23:59)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| DataPoint Un-verified. | (b) (4), (b) (6)               | 21 Apr 2021 14:17:24 |
| DataPoint Verified.    | (b) (4), (b) (6)               | 21 Apr 2021 14:12:09 |
| User entered empty.    | Diana Toney (b) (4)<br>(b) (4) | 13 Apr 2021 15:24:43 |



**US3222220**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:05:20**

[AE End Date and Time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 13 Apr 2021 15:24:43 |

US3222220

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:20

[Severity](#)

| Audit                            | User                           | Time (GMT)           |
|----------------------------------|--------------------------------|----------------------|
| DataPoint Verified.              | (b) (4), (b) (6)               | 21 Apr 2021 14:12:09 |
| User entered 'Grade 4 (Grade 4)' | Diana Toney (b) (4)<br>(b) (4) | 13 Apr 2021 15:24:43 |

US3222220

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:20

[Is the adverse event serious?](#)

| Audit                  | User                           | Time (GMT)           |
|------------------------|--------------------------------|----------------------|
| DataPoint Verified.    | (b) (4), (b) (6)               | 21 Apr 2021 14:12:09 |
| User entered 'Yes (Y)' | Diana Toney (b) (4)<br>(b) (4) | 13 Apr 2021 15:24:43 |

US3222220

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:20

[Death](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 21 Apr 2021 14:12:09 |
| User entered '0'    | Diana Toney (b) (4)<br>(b) (4) | 13 Apr 2021 15:24:43 |

US3222220

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:20

[Life threatening](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 21 Apr 2021 14:12:09 |
| User entered '0'    | Diana Toney (b) (4)<br>(b) (4) | 13 Apr 2021 15:24:43 |

US3222220

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:20

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit   | User                           | Time (GMT)           |
|---|--------------------------------|----------------------|
| DataPoint Un-verified.  | (b) (4), (b) (6)               | 21 Apr 2021 14:17:16 |
| DataPoint Verified.   | (b) (4), (b) (6)               | 21 Apr 2021 14:12:09 |
| User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).                             | (b) (4), (b) (6)               | 15 Apr 2021 09:47:48 |
| Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'pending medical records' (Site from System). | Diana Toney (b) (4)<br>(b) (4) | 13 Apr 2021 15:24:56 |
| User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).                             | System                         | 13 Apr 2021 15:24:43 |
| User entered 'I'  | Diana Toney (b) (4)<br>(b) (4) | 13 Apr 2021 15:24:43 |

US3222220

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:20

Hospital Admission Date (*dd MMM yyyy*)

| Audit   | User                           | Time (GMT)           |
|---|--------------------------------|----------------------|
| User opened query 'PV Query: Please update hospital admission date to the event, Fall.' (Site from Safety). | (b) (4), (b) (6)               | 22 Apr 2021 14:37:18 |
| DataPoint Un-verified.  | (b) (4), (b) (6)               | 21 Apr 2021 14:13:11 |
| DataPoint Verified.   | (b) (4), (b) (6)               | 21 Apr 2021 14:12:09 |
| User entered empty.   | Diana Toney (b) (4)<br>(b) (4) | 13 Apr 2021 15:24:43 |

US3222220

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:20

Hospital Discharge Date (*dd MMM yyyy*)

| Audit   | User                           | Time (GMT)           |
|---|--------------------------------|----------------------|
| User opened query 'PV Query: Please update hospital discharge date to the event, Fall.' (Site from Safety). | (b) (4), (b) (6)               | 03 May 2021 14:32:08 |
| DataPoint Un-verified.  | (b) (4), (b) (6)               | 21 Apr 2021 14:13:13 |
| DataPoint Verified.   | (b) (4), (b) (6)               | 21 Apr 2021 14:12:09 |
| User entered empty.   | Diana Toney (b) (4)<br>(b) (4) | 13 Apr 2021 15:24:43 |



US3222220

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:20

[Admitted to ICU?](#)

| Audit  | User                | Time (GMT)           |
|--|---------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6)    | 21 Apr 2021 14:12:09 |
| User opened query 'Per CDM: Please verify that Requires inpatient or prolongation of existing Hospitalization is checked however Admitted to ICU? should be YES or NO. Please review and updated accordingly. Else clarify.' (Site from DM). User entered empty. | (b) (4), (b) (6)    | 15 Apr 2021 09:48:14 |
|  | Diana Toney (b) (4) | 13 Apr 2021 15:24:43 |
|  | (b) (4)             |                      |

US3222220

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:20

[Number of Days in ICU](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 21 Apr 2021 14:12:09 |
| User entered empty. | Diana Toney (b) (4)<br>(b) (4) | 13 Apr 2021 15:24:43 |

US3222220

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:20

[Persistent or significant disability or incapacity](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 21 Apr 2021 14:12:09 |
| User entered '0'    | Diana Toney (b) (4)<br>(b) (4) | 13 Apr 2021 15:24:43 |

US3222220

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:20

[Congenital anomaly or birth defect](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 21 Apr 2021 14:12:09 |
| User entered '0'    | Diana Toney (b) (4)<br>(b) (4) | 13 Apr 2021 15:24:43 |

US3222220

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:20

[Other medically important event](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 21 Apr 2021 14:12:09 |
| User entered '0'    | Diana Toney (b) (4)<br>(b) (4) | 13 Apr 2021 15:24:43 |

US3222220

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:20

[Relationship to investigational product](#)

| Audit                                    | User                           | Time (GMT)           |
|--|--------------------------------|----------------------|
| DataPoint Verified.                      | (b) (4), (b) (6)               | 21 Apr 2021 14:12:09 |
| User entered 'Not Related (NOT RELATED)' | Diana Toney (b) (4)<br>(b) (4) | 13 Apr 2021 15:24:43 |

US3222220

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:20

[Relationship to Study Procedure](#)

| Audit                                    | User                           | Time (GMT)           |
|--|--------------------------------|----------------------|
| DataPoint Verified.                      | (b) (4), (b) (6)               | 21 Apr 2021 14:12:09 |
| User entered 'Not Related (NOT RELATED)' | Diana Toney (b) (4)<br>(b) (4) | 13 Apr 2021 15:24:43 |

US3222220

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:20

[Action taken with investigational product](#)

| Audit  | User                           | Time (GMT)           |
|--|--------------------------------|----------------------|
| DataPoint Verified.                            | (b) (4), (b) (6)               | 21 Apr 2021 14:12:09 |
| User entered 'Not Applicable (NOT APPLICABLE)' | Diana Toney (b) (4)<br>(b) (4) | 13 Apr 2021 15:24:43 |



US3222220

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:20

None

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 21 Apr 2021 14:12:09 |
| User entered '0'    | Diana Toney (b) (4)<br>(b) (4) | 13 Apr 2021 15:24:43 |

US3222220

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:20

[Concomitant Medication](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 21 Apr 2021 14:12:09 |
| User entered '1'    | Diana Toney (b) (4)<br>(b) (4) | 13 Apr 2021 15:24:43 |

US3222220

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:20

[Concomitant Procedure](#)

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 21 Apr 2021 14:12:09 |
| User entered '0'    | Diana Toney (b) (4)<br>(b) (4) | 13 Apr 2021 15:24:43 |

US3222220

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:20

[Outcome](#)

| Audit   | User                | Time (GMT)           |
|---|---------------------|----------------------|
| User opened query 'Source indicates recovered/resolved. Please confirm and revise if necessary.' (Site from CRA).<br>DataPoint Un-verified. | (b) (4), (b) (6)    | 21 Apr 2021 14:17:10 |
| DataPoint Verified.   | (b) (4), (b) (6)    | 21 Apr 2021 14:16:49 |
| User entered 'Unknown (UNKNOWN)'  | (b) (4), (b) (6)    | 21 Apr 2021 14:12:09 |
|   | Diana Toney (b) (4) | 13 Apr 2021 15:24:43 |
|   | (b) (4)             |                      |

US3222220

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:20

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit               | User                           | Time (GMT)           |
|---------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6)               | 21 Apr 2021 14:12:09 |
| User entered empty. | Diana Toney (b) (4)<br>(b) (4) | 13 Apr 2021 15:24:43 |

US3222220

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:20

[Narrative](#)

| Audit  | User                | Time (GMT)           |
|--|---------------------|----------------------|
| Query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' canceled (Site from Safety).        | (b) (4), (b) (6)    | 03 May 2021 14:30:42 |
| User opened query 'PV Query: What was the reason for the fall? (i.e. mechanical, accidental, underlying condition, etc)' (Site from Safety). | (b) (4), (b) (6)    | 03 May 2021 14:30:07 |
| User opened query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).     | (b) (4), (b) (6)    | 03 May 2021 14:29:48 |
| DataPoint Verified.  | (b) (4), (b) (6)    | 21 Apr 2021 14:12:09 |
| User entered 'SAE hospitalized 12/MAR/2021' reason for change: Data Entry Error  | Diana Toney (b) (4) | 13 Apr 2021 15:28:57 |
| User entered empty.  | (b) (4)             |                      |
|  | Diana Toney (b) (4) | 13 Apr 2021 15:24:43 |
|  | (b) (4)             |                      |

US3222220

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:20

Serious Adverse Event Derived (CSA Programming Field Only)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 13 Apr 2021 15:24:43 |

US3222220

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:05:20

Medically Attended AE Derived (CSA Programming Field Only)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'I' | System | 13 Apr 2021 15:24:43 |



US3222220

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 16:05:20

[Were any prior/concomitant medications and/or vaccinations taken?](#)

| Audit  | User                             | Time (GMT)           |
|--|----------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                 | 03 May 2021 15:40:10 |
| User signature succeeded.                                  | Bruce Rankin (b) (4)             | 19 Feb 2021 22:18:05 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | (b) (4)<br>(b) (4), (b) (6)      | 29 Oct 2020 13:38:10 |
| User entered 'No (N)'                                      | Amber Vasquez (b) (4)<br>(b) (4) | 09 Oct 2020 20:17:40 |

US3222220

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:05:20

Name of Medication

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| User signature succeeded.   | Bruce Rankin (b) (4)  | 19 Feb 2021 22:18:05 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE SODIUM SESQUIHYDRATE, PRODUCTSYNONYM: PROTONIX [PANTOPRAZOLE SODIUM SESQUIHYDRATE] - version WHODrug-Global-B3\202003. | Coder Import (b) (4)  | 03 Dec 2020 16:32:02 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.  | Coder Import (b) (4)  | 03 Dec 2020 16:32:02 |
| Data point term sent to Coder   | System                | 03 Dec 2020 16:31:08 |
| User closed query 'CDM-Coding: The trade name protonix can be referenced with multiple ingredients in the standard coding dictionary. Please enter the active ingredient(s) with the drug name. ' (Site from System).   | System                | 03 Dec 2020 16:30:28 |
| Query 'CDM-Coding: The trade name protonix can be referenced with multiple ingredients in the standard coding dictionary. Please enter the active ingredient(s) with the drug name. ' answered with 'pantoprazole sodium IS THE ACTIVE INGREDIANT WITH SEVERAL OTHER INACTIVE INGREDIENTS AS DO ALL MEDICATIONS' (Site from System).                      | Albert Garcia (b) (4) | 03 Dec 2020 16:30:28 |
| User entered 'PROTONIX' reason for change: Data Entry Error   | Albert Garcia (b) (4) | 03 Dec 2020 16:30:08 |
| User opened query 'CDM-Coding: The trade name protonix can be referenced with multiple ingredients in the standard coding dictionary. Please enter the active ingredient(s) with the drug name. ' (Site from System).   | Coder Import (b) (4)  | 23 Nov 2020 08:40:08 |
| Data point term sent to Coder   | System                | 29 Oct 2020 13:40:39 |
| User entered 'PROTONIX'   | (b) (4), (b) (6)      | 29 Oct 2020 13:39:42 |

US3222220

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:05:20

[Prophylaxis](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4)        | 19 Feb 2021 22:18:05 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 29 Oct 2020 13:39:42 |

US3222220

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:05:20

[Indication](#)

| Audit   | User                             | Time (GMT)           |
|---|----------------------------------|----------------------|
| User signature succeeded.   | Bruce Rankin (b) (4)             | 19 Feb 2021 22:18:05 |
| User closed query 'Per CDM: Indication of GERD is listed however, there is no corresponding Medical History or Adverse Event record present. Kindly review and reconcile as appropriate.' (Site from DM).             | (b) (4)<br>(b) (4), (b) (6)      | 24 Dec 2020 13:21:22 |
| Query 'Per CDM: Indication of GERD is listed however, there is no corresponding Medical History or Adverse Event record present. Kindly review and reconcile as appropriate.' answered with 'UPDATED' (Site from DM). | Albert Garcia (b) (4)<br>(b) (4) | 19 Dec 2020 12:53:06 |
| User opened query 'Per CDM: Indication of GERD is listed however, there is no corresponding Medical History or Adverse Event record present. Kindly review and reconcile as appropriate.' (Site from DM).             | (b) (4), (b) (6)                 | 09 Dec 2020 20:22:27 |
| User entered 'GERD'   | (b) (4), (b) (6)                 | 29 Oct 2020 13:39:42 |

US3222220

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:05:20**

[Dose per administration](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4)        | 19 Feb 2021 22:18:05 |
| User entered '40'         | (b) (4)<br>(b) (4), (b) (6) | 29 Oct 2020 13:39:42 |

US3222220

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:05:20

[Dose unit](#)

| Audit  | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| User signature succeeded.                                  | Bruce Rankin (b) (4)  | 19 Feb 2021 22:18:05 |
|  | (b) (4)               |                      |
| User entered 'mg (mg)' reason for change: Data Entry Error | Albert Garcia (b) (4) | 03 Dec 2020 16:30:08 |
|  | (b) (4)               |                      |
| User entered 'g (g)'                                       | (b) (4), (b) (6)      | 29 Oct 2020 13:39:42 |
|  |                       |                      |

US3222220

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:05:20**

If dose unit is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4)        | 19 Feb 2021 22:18:05 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 29 Oct 2020 13:39:42 |

US3222220

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:05:20

[Frequency](#)

| Audit                          | User                        | Time (GMT)           |
|--------------------------------|-----------------------------|----------------------|
| User signature succeeded.      | Bruce Rankin (b) (4)        | 19 Feb 2021 22:18:05 |
| User entered 'as needed (PRN)' | (b) (4)<br>(b) (4), (b) (6) | 29 Oct 2020 13:39:42 |



US3222220

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:05:20**

[If frequency is Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4)        | 19 Feb 2021 22:18:05 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 29 Oct 2020 13:39:42 |

US3222220

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:05:20**

[Route of administration](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | Bruce Rankin (b) (4)        | 19 Feb 2021 22:18:05 |
| User entered 'Oral (ORAL)' | (b) (4)<br>(b) (4), (b) (6) | 29 Oct 2020 13:39:42 |

US3222220

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:05:20**

If route of administration is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4)        | 19 Feb 2021 22:18:05 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 29 Oct 2020 13:39:42 |

US3222220

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:05:20**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | Bruce Rankin (b) (4)        | 19 Feb 2021 22:18:05 |
| User entered 'UN UNK 2019' | (b) (4)<br>(b) (4), (b) (6) | 29 Oct 2020 13:39:42 |

US3222220

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:05:20**

[Start date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4)        | 19 Feb 2021 22:18:05 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 29 Oct 2020 13:39:42 |

US3222220

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:05:20**

[Ongoing?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4)        | 19 Feb 2021 22:18:05 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 29 Oct 2020 13:39:42 |

US3222220

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:05:20**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4)        | 19 Feb 2021 22:18:05 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 29 Oct 2020 13:39:42 |

US3222220

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:05:20**

[Was this medication taken for solicited event?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4)        | 19 Feb 2021 22:18:05 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 29 Oct 2020 13:39:42 |



US3222220

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:05:20**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 29 Oct 2020 13:39:42 |

US3222220

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:05:20**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 29 Oct 2020 13:39:42 |

US3222220

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:05:20**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 29 Oct 2020 13:39:42 |

US3222220

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 09 Jun 2021 16:05:20**

[Were any concomitant procedures performed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4)        | 19 Feb 2021 22:18:05 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 09 Oct 2020 20:17:50 |

US3222220

Folder: SAE USA-US104-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:20

[SAEID](#)

| Audit                                 | User                 | Time (GMT)           |
|---------------------------------------|----------------------|----------------------|
| User signature succeeded.             | Bruce Rankin (b) (4) | 26 Apr 2021 13:56:59 |
| DataPoint Verified.                   | (b) (4)              |                      |
|                                       | (b) (4), (b) (6)     | 21 Apr 2021 14:09:24 |
| Reviewed for Safety.                  | (b) (4), (b) (6)     | 07 Apr 2021 15:09:37 |
| Un-reviewed for Safety.               | (b) (4), (b) (6)     | 07 Apr 2021 15:09:33 |
| Reviewed for Safety.                  | (b) (4), (b) (6)     | 17 Mar 2021 14:13:58 |
| User entered                          | System               | 17 Mar 2021 14:11:45 |
| 'USA-US104-2021-MRNA-1273-P301000015' |                      |                      |

US3222220

Folder: SAE USA-US104-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:20

Serious

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 13:56:59 |
| DataPoint Verified.       | (b) (4)              |                      |
|                           | (b) (4), (b) (6)     | 21 Apr 2021 14:09:24 |
| Reviewed for Safety.      | (b) (4), (b) (6)     | 07 Apr 2021 15:09:37 |
| User entered 'Yes (Y)'    | System               | 17 Mar 2021 14:11:45 |

US3222220

Folder: SAE USA-US104-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:20

Death

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 13:56:59 |
| DataPoint Verified.       | (b) (4)              |                      |
|                           | (b) (4), (b) (6)     | 21 Apr 2021 14:09:24 |
| Reviewed for Safety.      | (b) (4), (b) (6)     | 07 Apr 2021 15:09:37 |
| User entered 'No (N)'     | System               | 17 Mar 2021 14:11:45 |

US3222220

Folder: SAE USA-US104-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:20

[Life threatening](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 13:56:59 |
| DataPoint Verified.       | (b) (4)              |                      |
|                           | (b) (4), (b) (6)     | 21 Apr 2021 14:09:24 |
| Reviewed for Safety.      | (b) (4), (b) (6)     | 07 Apr 2021 15:09:37 |
| User entered 'No (N)'     | System               | 17 Mar 2021 14:11:45 |



US3222220

Folder: SAE USA-US104-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:20

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 13:56:59 |
| DataPoint Verified.       | (b) (4)              |                      |
|                           | (b) (4), (b) (6)     | 21 Apr 2021 14:09:24 |
| Reviewed for Safety.      | (b) (4), (b) (6)     | 07 Apr 2021 15:09:37 |
| User entered 'Yes (Y)'    | System               | 17 Mar 2021 14:11:45 |

US3222220

Folder: SAE USA-US104-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:20

[Persistent or significant disability or incapacity](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 13:56:59 |
| DataPoint Verified.       | (b) (4)              |                      |
|                           | (b) (4), (b) (6)     | 21 Apr 2021 14:09:24 |
| Reviewed for Safety.      | (b) (4), (b) (6)     | 07 Apr 2021 15:09:37 |
| User entered 'No (N)'     | System               | 17 Mar 2021 14:11:45 |

US3222220

Folder: SAE USA-US104-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:20

[Congenital anomaly or birth defect](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 13:56:59 |
| DataPoint Verified.       | (b) (4)              |                      |
|                           | (b) (4), (b) (6)     | 21 Apr 2021 14:09:24 |
| Reviewed for Safety.      | (b) (4), (b) (6)     | 07 Apr 2021 15:09:37 |
| User entered 'No (N)'     | System               | 17 Mar 2021 14:11:45 |

US3222220

Folder: SAE USA-US104-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:20

[Other medically important event](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 13:56:59 |
| DataPoint Verified.       | (b) (4)              |                      |
|                           | (b) (4), (b) (6)     | 21 Apr 2021 14:09:24 |
| Reviewed for Safety.      | (b) (4), (b) (6)     | 07 Apr 2021 15:09:37 |
| User entered 'No (N)'     | System               | 17 Mar 2021 14:11:45 |

US3222220

Folder: SAE USA-US104-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:20

[Investigator's First Name](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 13:56:59 |
| DataPoint Verified.       | (b) (4)              |                      |
|                           | (b) (4), (b) (6)     | 21 Apr 2021 14:09:24 |
| Reviewed for Safety.      | (b) (4), (b) (6)     | 07 Apr 2021 15:09:37 |
| User entered 'Bruce'      | System               | 17 Mar 2021 14:11:45 |

US3222220

Folder: SAE USA-US104-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:20

[Investigator's Last Name](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 13:56:59 |
| DataPoint Verified.       | (b) (4)              |                      |
|                           | (b) (4), (b) (6)     | 21 Apr 2021 14:09:24 |
| Reviewed for Safety.      | (b) (4), (b) (6)     | 07 Apr 2021 15:09:37 |
| User entered 'Rankin'     | System               | 17 Mar 2021 14:11:45 |

**US3222220**

**Folder: SAE USA-US104-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:05:20**

[Site Address: Street](#)

| Audit                            | User                 | Time (GMT)           |
|----------------------------------|----------------------|----------------------|
| User signature succeeded.        | Bruce Rankin (b) (4) | 26 Apr 2021 13:56:59 |
| DataPoint Verified.              | (b) (4)              |                      |
|                                  | (b) (4), (b) (6)     | 21 Apr 2021 14:09:24 |
| Reviewed for Safety.             | (b) (4), (b) (6)     | 07 Apr 2021 15:09:37 |
| User entered '860 Peachwood Ave' | System               | 17 Mar 2021 14:11:45 |

US3222220

Folder: SAE USA-US104-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:20

Site Address: [City](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 13:56:59 |
| DataPoint Verified.       | (b) (4)              |                      |
|                           | (b) (4), (b) (6)     | 21 Apr 2021 14:09:24 |
| Reviewed for Safety.      | (b) (4), (b) (6)     | 07 Apr 2021 15:09:37 |
| User entered 'Deland'     | System               | 17 Mar 2021 14:11:45 |



US3222220

Folder: SAE USA-US104-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:20

Site Address: State

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| User signature succeeded.  | Bruce Rankin (b) (4)   | 28 Apr 2021 22:12:59 |
| Reviewed for Safety.       | (b) (4)                |                      |
|                            | (b) (4), (b) (6)       | 26 Apr 2021 17:52:44 |
| Signature has been broken. | System                 | 26 Apr 2021 17:52:41 |
| User entered empty.        | System                 | 26 Apr 2021 17:52:41 |
| User signature succeeded.  | Bruce Rankin (b) (4)   | 26 Apr 2021 13:56:59 |
|                            | (b) (4)                |                      |
| User entered 'FL'          | douglas winter (b) (4) | 23 Apr 2021 20:23:35 |
|                            | (b) (4)                |                      |

US3222220

Folder: SAE USA-US104-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:20

Site Address: [Postal Code](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 13:56:59 |
| DataPoint Verified.       | (b) (4)              |                      |
|                           | (b) (4), (b) (6)     | 21 Apr 2021 14:09:24 |
| Reviewed for Safety.      | (b) (4), (b) (6)     | 07 Apr 2021 15:09:37 |
| User entered '32720'      | System               | 17 Mar 2021 14:11:45 |

US3222220

Folder: SAE USA-US104-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:20

[Investigator Country](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 13:56:59 |
| DataPoint Verified.       | (b) (4)              |                      |
|                           | (b) (4), (b) (6)     | 21 Apr 2021 14:09:24 |
| Reviewed for Safety.      | (b) (4), (b) (6)     | 07 Apr 2021 15:09:37 |
| User entered 'US'         | System               | 17 Mar 2021 14:14:05 |

**US3222220**

**Folder: SAE USA-US104-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:05:20**

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '5' | System | 26 Apr 2021 17:52:41 |
| User entered '4' | System | 15 Apr 2021 13:32:11 |
| User entered '3' | System | 14 Apr 2021 13:22:04 |
| User entered '2' | System | 07 Apr 2021 15:09:51 |
| User entered '1' | System | 17 Mar 2021 14:14:05 |

US3222220

Folder: SAE USA-US104-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:20

[SAEID](#)

| Audit                                 | User                 | Time (GMT)           |
|---------------------------------------|----------------------|----------------------|
| User signature succeeded.             | Bruce Rankin (b) (4) | 26 Apr 2021 13:56:59 |
| DataPoint Verified.                   | (b) (4)              |                      |
|                                       | (b) (4), (b) (6)     | 21 Apr 2021 14:09:24 |
| Reviewed for Safety.                  | (b) (4), (b) (6)     | 07 Apr 2021 15:09:37 |
| Un-reviewed for Safety.               | (b) (4), (b) (6)     | 07 Apr 2021 15:09:33 |
| Reviewed for Safety.                  | (b) (4), (b) (6)     | 17 Mar 2021 14:13:58 |
| User entered                          | System               | 17 Mar 2021 14:11:45 |
| 'USA-US104-2021-MRNA-1273-P301000015' |                      |                      |

US3222220

Folder: SAE USA-US104-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:20

Serious

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 13:56:59 |
| DataPoint Verified.       | (b) (4)              |                      |
|                           | (b) (4), (b) (6)     | 21 Apr 2021 14:09:24 |
| Reviewed for Safety.      | (b) (4), (b) (6)     | 07 Apr 2021 15:09:37 |
| User entered 'Yes (Y)'    | System               | 17 Mar 2021 14:11:45 |

**US3222220**

**Folder: SAE USA-US104-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:05:20**

[Death](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 13:56:59 |
| DataPoint Verified.       | (b) (4)              |                      |
|                           | (b) (4), (b) (6)     | 21 Apr 2021 14:09:24 |
| Reviewed for Safety.      | (b) (4), (b) (6)     | 07 Apr 2021 15:09:37 |
| User entered 'No (N)'     | System               | 17 Mar 2021 14:11:45 |

US3222220

Folder: SAE USA-US104-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:20

[Life threatening](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 13:56:59 |
| DataPoint Verified.       | (b) (4)              |                      |
|                           | (b) (4), (b) (6)     | 21 Apr 2021 14:09:24 |
| Reviewed for Safety.      | (b) (4), (b) (6)     | 07 Apr 2021 15:09:37 |
| User entered 'No (N)'     | System               | 17 Mar 2021 14:11:45 |



US3222220

Folder: SAE USA-US104-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:20

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4)        | 26 Apr 2021 13:56:59 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 21 Apr 2021 14:09:24 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 07 Apr 2021 15:09:37 |
| User entered 'Yes (Y)'    | System                      | 17 Mar 2021 14:11:45 |

US3222220

Folder: SAE USA-US104-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:20

[Persistent or significant disability or incapacity](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 13:56:59 |
| DataPoint Verified.       | (b) (4)              |                      |
|                           | (b) (4), (b) (6)     | 21 Apr 2021 14:09:24 |
| Reviewed for Safety.      | (b) (4), (b) (6)     | 07 Apr 2021 15:09:37 |
| User entered 'No (N)'     | System               | 17 Mar 2021 14:11:45 |

US3222220

Folder: SAE USA-US104-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:20

[Congenital anomaly or birth defect](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 13:56:59 |
| DataPoint Verified.       | (b) (4)              |                      |
|                           | (b) (4), (b) (6)     | 21 Apr 2021 14:09:24 |
| Reviewed for Safety.      | (b) (4), (b) (6)     | 07 Apr 2021 15:09:37 |
| User entered 'No (N)'     | System               | 17 Mar 2021 14:11:45 |

US3222220

Folder: SAE USA-US104-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:20

[Other medically important event](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 13:56:59 |
| DataPoint Verified.       | (b) (4)              |                      |
|                           | (b) (4), (b) (6)     | 21 Apr 2021 14:09:24 |
| Reviewed for Safety.      | (b) (4), (b) (6)     | 07 Apr 2021 15:09:37 |
| User entered 'No (N)'     | System               | 17 Mar 2021 14:11:45 |

US3222220

Folder: SAE USA-US104-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:20

[Investigator's First Name](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 13:56:59 |
| DataPoint Verified.       | (b) (4)              |                      |
|                           | (b) (4), (b) (6)     | 21 Apr 2021 14:09:24 |
| Reviewed for Safety.      | (b) (4), (b) (6)     | 07 Apr 2021 15:09:37 |
| User entered 'Bruce'      | System               | 17 Mar 2021 14:11:45 |

US3222220

Folder: SAE USA-US104-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:20

[Investigator's Last Name](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 13:56:59 |
| DataPoint Verified.       | (b) (4)              |                      |
|                           | (b) (4), (b) (6)     | 21 Apr 2021 14:09:24 |
| Reviewed for Safety.      | (b) (4), (b) (6)     | 07 Apr 2021 15:09:37 |
| User entered 'Rankin'     | System               | 17 Mar 2021 14:11:45 |

US3222220

Folder: SAE USA-US104-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:20

Site Address: [Street](#)

| Audit                            | User                 | Time (GMT)           |
|----------------------------------|----------------------|----------------------|
| User signature succeeded.        | Bruce Rankin (b) (4) | 26 Apr 2021 13:56:59 |
| DataPoint Verified.              | (b) (4)              |                      |
|                                  | (b) (4), (b) (6)     | 21 Apr 2021 14:09:24 |
| Reviewed for Safety.             | (b) (4), (b) (6)     | 07 Apr 2021 15:09:37 |
| User entered '860 Peachwood Ave' | System               | 17 Mar 2021 14:11:45 |

US3222220

Folder: SAE USA-US104-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:20

Site Address: [City](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 13:56:59 |
| DataPoint Verified.       | (b) (4)              |                      |
|                           | (b) (4), (b) (6)     | 21 Apr 2021 14:09:24 |
| Reviewed for Safety.      | (b) (4), (b) (6)     | 07 Apr 2021 15:09:37 |
| User entered 'Deland'     | System               | 17 Mar 2021 14:11:45 |



US3222220

Folder: SAE USA-US104-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:20

Site Address: State

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| User signature succeeded.  | Bruce Rankin (b) (4)   | 28 Apr 2021 22:12:59 |
| Reviewed for Safety.       | (b) (4)                |                      |
|                            | (b) (4), (b) (6)       | 26 Apr 2021 17:52:44 |
| Signature has been broken. | System                 | 26 Apr 2021 17:52:41 |
| User entered empty.        | System                 | 26 Apr 2021 17:52:41 |
| User signature succeeded.  | Bruce Rankin (b) (4)   | 26 Apr 2021 13:56:59 |
|                            | (b) (4)                |                      |
| User entered 'FL'          | douglas winter (b) (4) | 23 Apr 2021 20:23:35 |
|                            | (b) (4)                |                      |

**US3222220**

**Folder: SAE USA-US104-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:05:20**

[Site Address: Postal Code](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 13:56:59 |
| DataPoint Verified.       | (b) (4)              |                      |
|                           | (b) (4), (b) (6)     | 21 Apr 2021 14:09:24 |
| Reviewed for Safety.      | (b) (4), (b) (6)     | 07 Apr 2021 15:09:37 |
| User entered '32720'      | System               | 17 Mar 2021 14:11:45 |

US3222220

Folder: SAE USA-US104-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:20

[Investigator Country](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 13:56:59 |
| DataPoint Verified.       | (b) (4)              |                      |
|                           | (b) (4), (b) (6)     | 21 Apr 2021 14:09:24 |
| Reviewed for Safety.      | (b) (4), (b) (6)     | 07 Apr 2021 15:09:37 |
| User entered 'US'         | System               | 17 Mar 2021 14:14:05 |

**US3222220**

**Folder: SAE USA-US104-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:05:20**

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '5' | System | 26 Apr 2021 17:52:41 |
| User entered '4' | System | 15 Apr 2021 13:32:11 |
| User entered '3' | System | 14 Apr 2021 13:22:04 |
| User entered '2' | System | 07 Apr 2021 15:09:51 |
| User entered '1' | System | 17 Mar 2021 14:14:05 |

**US3222220**

**Folder: SAE USA-US104-2021-MRNA-1273-P301000015**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 16:05:20**

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User                        | Time (GMT)           |
|----------------------------------|-----------------------------|----------------------|
| User signature succeeded.        | Bruce Rankin (b) (4)        | 26 Apr 2021 13:56:59 |
| DataPoint Verified.              | (b) (4)<br>(b) (4), (b) (6) | 21 Apr 2021 14:09:24 |
| User entered '17/Mar/2021 10:14' | System                      | 17 Mar 2021 14:14:05 |

US3222220

Folder: SAE USA-US104-2021-MRNA-1273-P301000015

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:05:20

**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. | Bruce Rankin (b) (4) | 26 Apr 2021 13:56:59 |
| DataPoint Verified.       | (b) (4)              |                      |
|                           | (b) (4), (b) (6)     | 21 Apr 2021 14:09:24 |
| Reviewed for Safety.      | (b) (4), (b) (6)     | 07 Apr 2021 15:09:37 |
| User entered 'I'          | (b) (4), (b) (6)     | 17 Mar 2021 14:14:05 |

US3222220

Folder: SAE USA-US104-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:20

[SAEID](#)

| Audit                                 | User                 | Time (GMT)           |
|---------------------------------------|----------------------|----------------------|
| User signature succeeded.             | Bruce Rankin (b) (4) | 26 Apr 2021 13:56:59 |
| DataPoint Verified.                   | (b) (4)              |                      |
|                                       | (b) (4), (b) (6)     | 21 Apr 2021 14:09:24 |
| Reviewed for Safety.                  | (b) (4), (b) (6)     | 07 Apr 2021 15:09:37 |
| Un-reviewed for Safety.               | (b) (4), (b) (6)     | 07 Apr 2021 15:09:33 |
| Reviewed for Safety.                  | (b) (4), (b) (6)     | 17 Mar 2021 14:13:58 |
| User entered                          | System               | 17 Mar 2021 14:11:45 |
| 'USA-US104-2021-MRNA-1273-P301000015' |                      |                      |

US3222220

Folder: SAE USA-US104-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:20

Serious

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 13:56:59 |
| DataPoint Verified.       | (b) (4)              |                      |
|                           | (b) (4), (b) (6)     | 21 Apr 2021 14:09:24 |
| Reviewed for Safety.      | (b) (4), (b) (6)     | 07 Apr 2021 15:09:37 |
| User entered 'Yes (Y)'    | System               | 17 Mar 2021 14:11:45 |



US3222220

Folder: SAE USA-US104-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:20

Death

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 13:56:59 |
| DataPoint Verified.       | (b) (4)              |                      |
|                           | (b) (4), (b) (6)     | 21 Apr 2021 14:09:24 |
| Reviewed for Safety.      | (b) (4), (b) (6)     | 07 Apr 2021 15:09:37 |
| User entered 'No (N)'     | System               | 17 Mar 2021 14:11:45 |

US3222220

Folder: SAE USA-US104-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:20

[Life threatening](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 13:56:59 |
| DataPoint Verified.       | (b) (4)              |                      |
|                           | (b) (4), (b) (6)     | 21 Apr 2021 14:09:24 |
| Reviewed for Safety.      | (b) (4), (b) (6)     | 07 Apr 2021 15:09:37 |
| User entered 'No (N)'     | System               | 17 Mar 2021 14:11:45 |

US3222220

Folder: SAE USA-US104-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:20

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 13:56:59 |
| DataPoint Verified.       | (b) (4)              |                      |
|                           | (b) (4), (b) (6)     | 21 Apr 2021 14:09:24 |
| Reviewed for Safety.      | (b) (4), (b) (6)     | 07 Apr 2021 15:09:37 |
| User entered 'Yes (Y)'    | System               | 17 Mar 2021 14:11:45 |

US3222220

Folder: SAE USA-US104-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:20

[Persistent or significant disability or incapacity](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 13:56:59 |
| DataPoint Verified.       | (b) (4)              |                      |
|                           | (b) (4), (b) (6)     | 21 Apr 2021 14:09:24 |
| Reviewed for Safety.      | (b) (4), (b) (6)     | 07 Apr 2021 15:09:37 |
| User entered 'No (N)'     | System               | 17 Mar 2021 14:11:45 |

US3222220

Folder: SAE USA-US104-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:20

[Congenital anomaly or birth defect](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 13:56:59 |
| DataPoint Verified.       | (b) (4)              |                      |
|                           | (b) (4), (b) (6)     | 21 Apr 2021 14:09:24 |
| Reviewed for Safety.      | (b) (4), (b) (6)     | 07 Apr 2021 15:09:37 |
| User entered 'No (N)'     | System               | 17 Mar 2021 14:11:45 |

US3222220

Folder: SAE USA-US104-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:20

[Other medically important event](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 13:56:59 |
| DataPoint Verified.       | (b) (4)              |                      |
|                           | (b) (4), (b) (6)     | 21 Apr 2021 14:09:24 |
| Reviewed for Safety.      | (b) (4), (b) (6)     | 07 Apr 2021 15:09:37 |
| User entered 'No (N)'     | System               | 17 Mar 2021 14:11:45 |

US3222220

Folder: SAE USA-US104-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:20

[Investigator's First Name](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 13:56:59 |
| DataPoint Verified.       | (b) (4)              |                      |
|                           | (b) (4), (b) (6)     | 21 Apr 2021 14:09:24 |
| Reviewed for Safety.      | (b) (4), (b) (6)     | 07 Apr 2021 15:09:37 |
| User entered 'Bruce'      | System               | 17 Mar 2021 14:11:45 |

US3222220

Folder: SAE USA-US104-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:20

[Investigator's Last Name](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 13:56:59 |
| DataPoint Verified.       | (b) (4)              |                      |
|                           | (b) (4), (b) (6)     | 21 Apr 2021 14:09:24 |
| Reviewed for Safety.      | (b) (4), (b) (6)     | 07 Apr 2021 15:09:37 |
| User entered 'Rankin'     | System               | 17 Mar 2021 14:11:45 |



US3222220

Folder: SAE USA-US104-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:20

Site Address: [Street](#)

| Audit                            | User                 | Time (GMT)           |
|----------------------------------|----------------------|----------------------|
| User signature succeeded.        | Bruce Rankin (b) (4) | 26 Apr 2021 13:56:59 |
| DataPoint Verified.              | (b) (4)              |                      |
|                                  | (b) (4), (b) (6)     | 21 Apr 2021 14:09:24 |
| Reviewed for Safety.             | (b) (4), (b) (6)     | 07 Apr 2021 15:09:37 |
| User entered '860 Peachwood Ave' | System               | 17 Mar 2021 14:11:45 |

US3222220

Folder: SAE USA-US104-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:20

Site Address: [City](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 13:56:59 |
| DataPoint Verified.       | (b) (4)              |                      |
|                           | (b) (4), (b) (6)     | 21 Apr 2021 14:09:24 |
| Reviewed for Safety.      | (b) (4), (b) (6)     | 07 Apr 2021 15:09:37 |
| User entered 'Deland'     | System               | 17 Mar 2021 14:11:45 |

US3222220

Folder: SAE USA-US104-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:20

Site Address: State

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| User signature succeeded.  | Bruce Rankin (b) (4)   | 28 Apr 2021 22:12:59 |
| Reviewed for Safety.       | (b) (4)                |                      |
|                            | (b) (4), (b) (6)       | 26 Apr 2021 17:52:44 |
| Signature has been broken. | System                 | 26 Apr 2021 17:52:41 |
| User entered empty.        | System                 | 26 Apr 2021 17:52:41 |
| User signature succeeded.  | Bruce Rankin (b) (4)   | 26 Apr 2021 13:56:59 |
|                            | (b) (4)                |                      |
| User entered 'FL'          | douglas winter (b) (4) | 23 Apr 2021 20:23:35 |
|                            | (b) (4)                |                      |

**US3222220**

**Folder: SAE USA-US104-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:05:20**

[Site Address: Postal Code](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4)        | 26 Apr 2021 13:56:59 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 21 Apr 2021 14:09:24 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 07 Apr 2021 15:09:37 |
| User entered '32720'      | System                      | 17 Mar 2021 14:11:45 |

US3222220

Folder: SAE USA-US104-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:20

[Investigator Country](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 13:56:59 |
| DataPoint Verified.       | (b) (4)              |                      |
|                           | (b) (4), (b) (6)     | 21 Apr 2021 14:09:24 |
| Reviewed for Safety.      | (b) (4), (b) (6)     | 07 Apr 2021 15:09:37 |
| User entered 'US'         | System               | 17 Mar 2021 14:14:05 |

**US3222220**

**Folder: SAE USA-US104-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:05:20**

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '5' | System | 26 Apr 2021 17:52:41 |
| User entered '4' | System | 15 Apr 2021 13:32:11 |
| User entered '3' | System | 14 Apr 2021 13:22:04 |
| User entered '2' | System | 07 Apr 2021 15:09:51 |
| User entered '1' | System | 17 Mar 2021 14:14:05 |

**US3222220**

**Folder: SAE USA-US104-2021-MRNA-1273-P301000015**

**Form: Safety Report Form (2)**

**Generated On: 09 Jun 2021 16:05:20**

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User                        | Time (GMT)           |
|----------------------------------|-----------------------------|----------------------|
| User signature succeeded.        | Bruce Rankin (b) (4)        | 26 Apr 2021 13:56:59 |
| DataPoint Verified.              | (b) (4)<br>(b) (4), (b) (6) | 21 Apr 2021 14:09:24 |
| User entered '07/Apr/2021 11:09' | System                      | 07 Apr 2021 15:09:51 |

US3222220

Folder: SAE USA-US104-2021-MRNA-1273-P301000015

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:05:20

**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. | Bruce Rankin (b) (4) | 26 Apr 2021 13:56:59 |
| DataPoint Verified.       | (b) (4)              |                      |
|                           | (b) (4), (b) (6)     | 21 Apr 2021 14:09:24 |
| Reviewed for Safety.      | (b) (4), (b) (6)     | 14 Apr 2021 13:21:38 |
| User entered 'I'          | (b) (4), (b) (6)     | 07 Apr 2021 15:09:51 |



US3222220

Folder: SAE USA-US104-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:20

[SAEID](#)

| Audit                                 | User                 | Time (GMT)           |
|---------------------------------------|----------------------|----------------------|
| User signature succeeded.             | Bruce Rankin (b) (4) | 26 Apr 2021 13:56:59 |
| DataPoint Verified.                   | (b) (4)              |                      |
|                                       | (b) (4), (b) (6)     | 21 Apr 2021 14:09:24 |
| Reviewed for Safety.                  | (b) (4), (b) (6)     | 07 Apr 2021 15:09:37 |
| Un-reviewed for Safety.               | (b) (4), (b) (6)     | 07 Apr 2021 15:09:33 |
| Reviewed for Safety.                  | (b) (4), (b) (6)     | 17 Mar 2021 14:13:58 |
| User entered                          | System               | 17 Mar 2021 14:11:45 |
| 'USA-US104-2021-MRNA-1273-P301000015' |                      |                      |

US3222220

Folder: SAE USA-US104-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:20

Serious

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 13:56:59 |
| DataPoint Verified.       | (b) (4)              |                      |
|                           | (b) (4), (b) (6)     | 21 Apr 2021 14:09:24 |
| Reviewed for Safety.      | (b) (4), (b) (6)     | 07 Apr 2021 15:09:37 |
| User entered 'Yes (Y)'    | System               | 17 Mar 2021 14:11:45 |

**US3222220**

**Folder: SAE USA-US104-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:05:20**

[Death](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 13:56:59 |
| DataPoint Verified.       | (b) (4)              |                      |
|                           | (b) (4), (b) (6)     | 21 Apr 2021 14:09:24 |
| Reviewed for Safety.      | (b) (4), (b) (6)     | 07 Apr 2021 15:09:37 |
| User entered 'No (N)'     | System               | 17 Mar 2021 14:11:45 |

US3222220

Folder: SAE USA-US104-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:20

[Life threatening](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 13:56:59 |
| DataPoint Verified.       | (b) (4)              |                      |
|                           | (b) (4), (b) (6)     | 21 Apr 2021 14:09:24 |
| Reviewed for Safety.      | (b) (4), (b) (6)     | 07 Apr 2021 15:09:37 |
| User entered 'No (N)'     | System               | 17 Mar 2021 14:11:45 |

US3222220

Folder: SAE USA-US104-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:20

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 13:56:59 |
| DataPoint Verified.       | (b) (4)              |                      |
|                           | (b) (4), (b) (6)     | 21 Apr 2021 14:09:24 |
| Reviewed for Safety.      | (b) (4), (b) (6)     | 07 Apr 2021 15:09:37 |
| User entered 'Yes (Y)'    | System               | 17 Mar 2021 14:11:45 |

US3222220

Folder: SAE USA-US104-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:20

[Persistent or significant disability or incapacity](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 13:56:59 |
| DataPoint Verified.       | (b) (4)              |                      |
|                           | (b) (4), (b) (6)     | 21 Apr 2021 14:09:24 |
| Reviewed for Safety.      | (b) (4), (b) (6)     | 07 Apr 2021 15:09:37 |
| User entered 'No (N)'     | System               | 17 Mar 2021 14:11:45 |

US3222220

Folder: SAE USA-US104-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:20

[Congenital anomaly or birth defect](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 13:56:59 |
| DataPoint Verified.       | (b) (4)              |                      |
|                           | (b) (4), (b) (6)     | 21 Apr 2021 14:09:24 |
| Reviewed for Safety.      | (b) (4), (b) (6)     | 07 Apr 2021 15:09:37 |
| User entered 'No (N)'     | System               | 17 Mar 2021 14:11:45 |

US3222220

Folder: SAE USA-US104-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:20

[Other medically important event](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 13:56:59 |
| DataPoint Verified.       | (b) (4)              |                      |
|                           | (b) (4), (b) (6)     | 21 Apr 2021 14:09:24 |
| Reviewed for Safety.      | (b) (4), (b) (6)     | 07 Apr 2021 15:09:37 |
| User entered 'No (N)'     | System               | 17 Mar 2021 14:11:45 |



US3222220

Folder: SAE USA-US104-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:20

[Investigator's First Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4)        | 26 Apr 2021 13:56:59 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 21 Apr 2021 14:09:24 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 07 Apr 2021 15:09:37 |
| User entered 'Bruce'      | System                      | 17 Mar 2021 14:11:45 |

US3222220

Folder: SAE USA-US104-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:20

[Investigator's Last Name](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 13:56:59 |
| DataPoint Verified.       | (b) (4)              |                      |
|                           | (b) (4), (b) (6)     | 21 Apr 2021 14:09:24 |
| Reviewed for Safety.      | (b) (4), (b) (6)     | 07 Apr 2021 15:09:37 |
| User entered 'Rankin'     | System               | 17 Mar 2021 14:11:45 |

US3222220

Folder: SAE USA-US104-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:20

Site Address: [Street](#)

| Audit                            | User                 | Time (GMT)           |
|----------------------------------|----------------------|----------------------|
| User signature succeeded.        | Bruce Rankin (b) (4) | 26 Apr 2021 13:56:59 |
| DataPoint Verified.              | (b) (4)              |                      |
|                                  | (b) (4), (b) (6)     | 21 Apr 2021 14:09:24 |
| Reviewed for Safety.             | (b) (4), (b) (6)     | 07 Apr 2021 15:09:37 |
| User entered '860 Peachwood Ave' | System               | 17 Mar 2021 14:11:45 |

US3222220

Folder: SAE USA-US104-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:20

Site Address: [City](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 13:56:59 |
| DataPoint Verified.       | (b) (4)              |                      |
|                           | (b) (4), (b) (6)     | 21 Apr 2021 14:09:24 |
| Reviewed for Safety.      | (b) (4), (b) (6)     | 07 Apr 2021 15:09:37 |
| User entered 'Deland'     | System               | 17 Mar 2021 14:11:45 |

US3222220

Folder: SAE USA-US104-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:20

Site Address: State

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| User signature succeeded.  | Bruce Rankin (b) (4)   | 28 Apr 2021 22:12:59 |
| Reviewed for Safety.       | (b) (4)                |                      |
|                            | (b) (4), (b) (6)       | 26 Apr 2021 17:52:44 |
| Signature has been broken. | System                 | 26 Apr 2021 17:52:41 |
| User entered empty.        | System                 | 26 Apr 2021 17:52:41 |
| User signature succeeded.  | Bruce Rankin (b) (4)   | 26 Apr 2021 13:56:59 |
|                            | (b) (4)                |                      |
| User entered 'FL'          | douglas winter (b) (4) | 23 Apr 2021 20:23:35 |
|                            | (b) (4)                |                      |

US3222220

Folder: SAE USA-US104-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:20

Site Address: [Postal Code](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 13:56:59 |
| DataPoint Verified.       | (b) (4)              |                      |
|                           | (b) (4), (b) (6)     | 21 Apr 2021 14:09:24 |
| Reviewed for Safety.      | (b) (4), (b) (6)     | 07 Apr 2021 15:09:37 |
| User entered '32720'      | System               | 17 Mar 2021 14:11:45 |

US3222220

Folder: SAE USA-US104-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:20

[Investigator Country](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 13:56:59 |
| DataPoint Verified.       | (b) (4)              |                      |
|                           | (b) (4), (b) (6)     | 21 Apr 2021 14:09:24 |
| Reviewed for Safety.      | (b) (4), (b) (6)     | 07 Apr 2021 15:09:37 |
| User entered 'US'         | System               | 17 Mar 2021 14:14:05 |

**US3222220**

**Folder: SAE USA-US104-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:05:20**

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '5' | System | 26 Apr 2021 17:52:41 |
| User entered '4' | System | 15 Apr 2021 13:32:11 |
| User entered '3' | System | 14 Apr 2021 13:22:04 |
| User entered '2' | System | 07 Apr 2021 15:09:51 |
| User entered '1' | System | 17 Mar 2021 14:14:05 |



**US3222220**

**Folder: SAE USA-US104-2021-MRNA-1273-P301000015**

**Form: Safety Report Form (3)**

**Generated On: 09 Jun 2021 16:05:20**

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User                        | Time (GMT)           |
|----------------------------------|-----------------------------|----------------------|
| User signature succeeded.        | Bruce Rankin (b) (4)        | 26 Apr 2021 13:56:59 |
| DataPoint Verified.              | (b) (4)<br>(b) (4), (b) (6) | 21 Apr 2021 14:09:24 |
| User entered '14/Apr/2021 06:21' | System                      | 14 Apr 2021 13:22:04 |

US3222220

Folder: SAE USA-US104-2021-MRNA-1273-P301000015

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:05:20

**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. | Bruce Rankin (b) (4) | 26 Apr 2021 13:56:59 |
| DataPoint Verified.       | (b) (4)              |                      |
|                           | (b) (4), (b) (6)     | 21 Apr 2021 14:09:24 |
| Reviewed for Safety.      | (b) (4), (b) (6)     | 15 Apr 2021 13:31:37 |
| User entered 'I'          | (b) (4), (b) (6)     | 14 Apr 2021 13:22:04 |

US3222220

Folder: SAE USA-US104-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:20

[SAEID](#)

| Audit                                 | User                 | Time (GMT)           |
|---------------------------------------|----------------------|----------------------|
| User signature succeeded.             | Bruce Rankin (b) (4) | 26 Apr 2021 13:56:59 |
| DataPoint Verified.                   | (b) (4)              |                      |
|                                       | (b) (4), (b) (6)     | 21 Apr 2021 14:09:24 |
| Reviewed for Safety.                  | (b) (4), (b) (6)     | 07 Apr 2021 15:09:37 |
| Un-reviewed for Safety.               | (b) (4), (b) (6)     | 07 Apr 2021 15:09:33 |
| Reviewed for Safety.                  | (b) (4), (b) (6)     | 17 Mar 2021 14:13:58 |
| User entered                          | System               | 17 Mar 2021 14:11:45 |
| 'USA-US104-2021-MRNA-1273-P301000015' |                      |                      |

**US3222220**

**Folder: SAE USA-US104-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:05:20**

**Serious**

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 13:56:59 |
| DataPoint Verified.       | (b) (4)              |                      |
|                           | (b) (4), (b) (6)     | 21 Apr 2021 14:09:24 |
| Reviewed for Safety.      | (b) (4), (b) (6)     | 07 Apr 2021 15:09:37 |
| User entered 'Yes (Y)'    | System               | 17 Mar 2021 14:11:45 |

US3222220

Folder: SAE USA-US104-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:20

Death

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 13:56:59 |
| DataPoint Verified.       | (b) (4)              |                      |
|                           | (b) (4), (b) (6)     | 21 Apr 2021 14:09:24 |
| Reviewed for Safety.      | (b) (4), (b) (6)     | 07 Apr 2021 15:09:37 |
| User entered 'No (N)'     | System               | 17 Mar 2021 14:11:45 |

US3222220

Folder: SAE USA-US104-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:20

[Life threatening](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 13:56:59 |
| DataPoint Verified.       | (b) (4)              |                      |
|                           | (b) (4), (b) (6)     | 21 Apr 2021 14:09:24 |
| Reviewed for Safety.      | (b) (4), (b) (6)     | 07 Apr 2021 15:09:37 |
| User entered 'No (N)'     | System               | 17 Mar 2021 14:11:45 |

US3222220

Folder: SAE USA-US104-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:20

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 13:56:59 |
| DataPoint Verified.       | (b) (4)              |                      |
|                           | (b) (4), (b) (6)     | 21 Apr 2021 14:09:24 |
| Reviewed for Safety.      | (b) (4), (b) (6)     | 07 Apr 2021 15:09:37 |
| User entered 'Yes (Y)'    | System               | 17 Mar 2021 14:11:45 |

US3222220

Folder: SAE USA-US104-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:20

[Persistent or significant disability or incapacity](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 13:56:59 |
| DataPoint Verified.       | (b) (4)              |                      |
|                           | (b) (4), (b) (6)     | 21 Apr 2021 14:09:24 |
| Reviewed for Safety.      | (b) (4), (b) (6)     | 07 Apr 2021 15:09:37 |
| User entered 'No (N)'     | System               | 17 Mar 2021 14:11:45 |



US3222220

Folder: SAE USA-US104-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:20

[Congenital anomaly or birth defect](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 13:56:59 |
| DataPoint Verified.       | (b) (4)              |                      |
|                           | (b) (4), (b) (6)     | 21 Apr 2021 14:09:24 |
| Reviewed for Safety.      | (b) (4), (b) (6)     | 07 Apr 2021 15:09:37 |
| User entered 'No (N)'     | System               | 17 Mar 2021 14:11:45 |

US3222220

Folder: SAE USA-US104-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:20

[Other medically important event](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 13:56:59 |
| DataPoint Verified.       | (b) (4)              |                      |
|                           | (b) (4), (b) (6)     | 21 Apr 2021 14:09:24 |
| Reviewed for Safety.      | (b) (4), (b) (6)     | 07 Apr 2021 15:09:37 |
| User entered 'No (N)'     | System               | 17 Mar 2021 14:11:45 |

US3222220

Folder: SAE USA-US104-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:20

[Investigator's First Name](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 13:56:59 |
| DataPoint Verified.       | (b) (4)              |                      |
|                           | (b) (4), (b) (6)     | 21 Apr 2021 14:09:24 |
| Reviewed for Safety.      | (b) (4), (b) (6)     | 07 Apr 2021 15:09:37 |
| User entered 'Bruce'      | System               | 17 Mar 2021 14:11:45 |

US3222220

Folder: SAE USA-US104-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:20

[Investigator's Last Name](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 13:56:59 |
| DataPoint Verified.       | (b) (4)              |                      |
|                           | (b) (4), (b) (6)     | 21 Apr 2021 14:09:24 |
| Reviewed for Safety.      | (b) (4), (b) (6)     | 07 Apr 2021 15:09:37 |
| User entered 'Rankin'     | System               | 17 Mar 2021 14:11:45 |

US3222220

Folder: SAE USA-US104-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:20

Site Address: [Street](#)

| Audit                            | User                 | Time (GMT)           |
|----------------------------------|----------------------|----------------------|
| User signature succeeded.        | Bruce Rankin (b) (4) | 26 Apr 2021 13:56:59 |
| DataPoint Verified.              | (b) (4)              |                      |
|                                  | (b) (4), (b) (6)     | 21 Apr 2021 14:09:24 |
| Reviewed for Safety.             | (b) (4), (b) (6)     | 07 Apr 2021 15:09:37 |
| User entered '860 Peachwood Ave' | System               | 17 Mar 2021 14:11:45 |

US3222220

Folder: SAE USA-US104-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:20

Site Address: [City](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 13:56:59 |
| DataPoint Verified.       | (b) (4)              |                      |
|                           | (b) (4), (b) (6)     | 21 Apr 2021 14:09:24 |
| Reviewed for Safety.      | (b) (4), (b) (6)     | 07 Apr 2021 15:09:37 |
| User entered 'Deland'     | System               | 17 Mar 2021 14:11:45 |

US3222220

Folder: SAE USA-US104-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:20

Site Address: State

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| User signature succeeded.  | Bruce Rankin (b) (4)   | 28 Apr 2021 22:12:59 |
| Reviewed for Safety.       | (b) (4)                |                      |
|                            | (b) (4), (b) (6)       | 26 Apr 2021 17:52:44 |
| Signature has been broken. | System                 | 26 Apr 2021 17:52:41 |
| User entered empty.        | System                 | 26 Apr 2021 17:52:41 |
| User signature succeeded.  | Bruce Rankin (b) (4)   | 26 Apr 2021 13:56:59 |
|                            | (b) (4)                |                      |
| User entered 'FL'          | douglas winter (b) (4) | 23 Apr 2021 20:23:35 |
|                            | (b) (4)                |                      |

**US3222220**

**Folder: SAE USA-US104-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:05:20**

[Site Address: Postal Code](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 13:56:59 |
| DataPoint Verified.       | (b) (4)              |                      |
|                           | (b) (4), (b) (6)     | 21 Apr 2021 14:09:24 |
| Reviewed for Safety.      | (b) (4), (b) (6)     | 07 Apr 2021 15:09:37 |
| User entered '32720'      | System               | 17 Mar 2021 14:11:45 |



US3222220

Folder: SAE USA-US104-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:20

[Investigator Country](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 13:56:59 |
| DataPoint Verified.       | (b) (4)              |                      |
|                           | (b) (4), (b) (6)     | 21 Apr 2021 14:09:24 |
| Reviewed for Safety.      | (b) (4), (b) (6)     | 07 Apr 2021 15:09:37 |
| User entered 'US'         | System               | 17 Mar 2021 14:14:05 |

**US3222220**

**Folder: SAE USA-US104-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:05:20**

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '5' | System | 26 Apr 2021 17:52:41 |
| User entered '4' | System | 15 Apr 2021 13:32:11 |
| User entered '3' | System | 14 Apr 2021 13:22:04 |
| User entered '2' | System | 07 Apr 2021 15:09:51 |
| User entered '1' | System | 17 Mar 2021 14:14:05 |

**US3222220**

**Folder: SAE USA-US104-2021-MRNA-1273-P301000015**

**Form: Safety Report Form (4)**

**Generated On: 09 Jun 2021 16:05:20**

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User                        | Time (GMT)           |
|----------------------------------|-----------------------------|----------------------|
| User signature succeeded.        | Bruce Rankin (b) (4)        | 26 Apr 2021 13:56:59 |
| DataPoint Verified.              | (b) (4)<br>(b) (4), (b) (6) | 21 Apr 2021 14:09:24 |
| User entered '15/Apr/2021 09:32' | System                      | 15 Apr 2021 13:32:11 |

US3222220

Folder: SAE USA-US104-2021-MRNA-1273-P301000015

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:05:20

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Reviewed for Safety.      | (b) (4), (b) (6)            | 26 Apr 2021 17:52:44 |
| User signature succeeded. | Bruce Rankin (b) (4)        | 26 Apr 2021 13:56:59 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 21 Apr 2021 14:09:24 |
| User entered 'I'          | (b) (4), (b) (6)            | 15 Apr 2021 13:32:11 |

US3222220

Folder: SAE USA-US104-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:20

[SAEID](#)

| Audit                                 | User                 | Time (GMT)           |
|---------------------------------------|----------------------|----------------------|
| User signature succeeded.             | Bruce Rankin (b) (4) | 26 Apr 2021 13:56:59 |
| DataPoint Verified.                   | (b) (4)              |                      |
|                                       | (b) (4), (b) (6)     | 21 Apr 2021 14:09:24 |
| Reviewed for Safety.                  | (b) (4), (b) (6)     | 07 Apr 2021 15:09:37 |
| Un-reviewed for Safety.               | (b) (4), (b) (6)     | 07 Apr 2021 15:09:33 |
| Reviewed for Safety.                  | (b) (4), (b) (6)     | 17 Mar 2021 14:13:58 |
| User entered                          | System               | 17 Mar 2021 14:11:45 |
| 'USA-US104-2021-MRNA-1273-P301000015' |                      |                      |

US3222220

Folder: SAE USA-US104-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:20

Serious

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 13:56:59 |
| DataPoint Verified.       | (b) (4)              |                      |
|                           | (b) (4), (b) (6)     | 21 Apr 2021 14:09:24 |
| Reviewed for Safety.      | (b) (4), (b) (6)     | 07 Apr 2021 15:09:37 |
| User entered 'Yes (Y)'    | System               | 17 Mar 2021 14:11:45 |

US3222220

Folder: SAE USA-US104-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:20

Death

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4)        | 26 Apr 2021 13:56:59 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 21 Apr 2021 14:09:24 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 07 Apr 2021 15:09:37 |
| User entered 'No (N)'     | System                      | 17 Mar 2021 14:11:45 |

US3222220

Folder: SAE USA-US104-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:20

[Life threatening](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 13:56:59 |
| DataPoint Verified.       | (b) (4)              |                      |
|                           | (b) (4), (b) (6)     | 21 Apr 2021 14:09:24 |
| Reviewed for Safety.      | (b) (4), (b) (6)     | 07 Apr 2021 15:09:37 |
| User entered 'No (N)'     | System               | 17 Mar 2021 14:11:45 |



US3222220

Folder: SAE USA-US104-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:20

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 13:56:59 |
| DataPoint Verified.       | (b) (4)              |                      |
|                           | (b) (4), (b) (6)     | 21 Apr 2021 14:09:24 |
| Reviewed for Safety.      | (b) (4), (b) (6)     | 07 Apr 2021 15:09:37 |
| User entered 'Yes (Y)'    | System               | 17 Mar 2021 14:11:45 |

US3222220

Folder: SAE USA-US104-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:20

[Persistent or significant disability or incapacity](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 13:56:59 |
| DataPoint Verified.       | (b) (4)              |                      |
|                           | (b) (4), (b) (6)     | 21 Apr 2021 14:09:24 |
| Reviewed for Safety.      | (b) (4), (b) (6)     | 07 Apr 2021 15:09:37 |
| User entered 'No (N)'     | System               | 17 Mar 2021 14:11:45 |

US3222220

Folder: SAE USA-US104-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:20

[Congenital anomaly or birth defect](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 13:56:59 |
| DataPoint Verified.       | (b) (4)              |                      |
|                           | (b) (4), (b) (6)     | 21 Apr 2021 14:09:24 |
| Reviewed for Safety.      | (b) (4), (b) (6)     | 07 Apr 2021 15:09:37 |
| User entered 'No (N)'     | System               | 17 Mar 2021 14:11:45 |

US3222220

Folder: SAE USA-US104-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:20

[Other medically important event](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 13:56:59 |
| DataPoint Verified.       | (b) (4)              |                      |
|                           | (b) (4), (b) (6)     | 21 Apr 2021 14:09:24 |
| Reviewed for Safety.      | (b) (4), (b) (6)     | 07 Apr 2021 15:09:37 |
| User entered 'No (N)'     | System               | 17 Mar 2021 14:11:45 |

US3222220

Folder: SAE USA-US104-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:20

[Investigator's First Name](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 13:56:59 |
| DataPoint Verified.       | (b) (4)              |                      |
|                           | (b) (4), (b) (6)     | 21 Apr 2021 14:09:24 |
| Reviewed for Safety.      | (b) (4), (b) (6)     | 07 Apr 2021 15:09:37 |
| User entered 'Bruce'      | System               | 17 Mar 2021 14:11:45 |

US3222220

Folder: SAE USA-US104-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:20

[Investigator's Last Name](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 13:56:59 |
| DataPoint Verified.       | (b) (4)              |                      |
|                           | (b) (4), (b) (6)     | 21 Apr 2021 14:09:24 |
| Reviewed for Safety.      | (b) (4), (b) (6)     | 07 Apr 2021 15:09:37 |
| User entered 'Rankin'     | System               | 17 Mar 2021 14:11:45 |

US3222220

Folder: SAE USA-US104-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:20

Site Address: [Street](#)

| Audit                            | User                 | Time (GMT)           |
|----------------------------------|----------------------|----------------------|
| User signature succeeded.        | Bruce Rankin (b) (4) | 26 Apr 2021 13:56:59 |
| DataPoint Verified.              | (b) (4)              |                      |
|                                  | (b) (4), (b) (6)     | 21 Apr 2021 14:09:24 |
| Reviewed for Safety.             | (b) (4), (b) (6)     | 07 Apr 2021 15:09:37 |
| User entered '860 Peachwood Ave' | System               | 17 Mar 2021 14:11:45 |

US3222220

Folder: SAE USA-US104-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:20

Site Address: [City](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 13:56:59 |
| DataPoint Verified.       | (b) (4)              |                      |
|                           | (b) (4), (b) (6)     | 21 Apr 2021 14:09:24 |
| Reviewed for Safety.      | (b) (4), (b) (6)     | 07 Apr 2021 15:09:37 |
| User entered 'Deland'     | System               | 17 Mar 2021 14:11:45 |



US3222220

Folder: SAE USA-US104-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:20

Site Address: State

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| User signature succeeded.  | Bruce Rankin (b) (4)   | 28 Apr 2021 22:12:59 |
| Reviewed for Safety.       | (b) (4)                |                      |
|                            | (b) (4), (b) (6)       | 26 Apr 2021 17:52:44 |
| Signature has been broken. | System                 | 26 Apr 2021 17:52:41 |
| User entered empty.        | System                 | 26 Apr 2021 17:52:41 |
| User signature succeeded.  | Bruce Rankin (b) (4)   | 26 Apr 2021 13:56:59 |
|                            | (b) (4)                |                      |
| User entered 'FL'          | douglas winter (b) (4) | 23 Apr 2021 20:23:35 |
|                            | (b) (4)                |                      |

**US3222220**

**Folder: SAE USA-US104-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:05:20**

[Site Address: Postal Code](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 13:56:59 |
| DataPoint Verified.       | (b) (4)              |                      |
|                           | (b) (4), (b) (6)     | 21 Apr 2021 14:09:24 |
| Reviewed for Safety.      | (b) (4), (b) (6)     | 07 Apr 2021 15:09:37 |
| User entered '32720'      | System               | 17 Mar 2021 14:11:45 |

US3222220

Folder: SAE USA-US104-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:05:20

[Investigator Country](#)

| Audit                     | User                 | Time (GMT)           |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 13:56:59 |
| DataPoint Verified.       | (b) (4)              |                      |
|                           | (b) (4), (b) (6)     | 21 Apr 2021 14:09:24 |
| Reviewed for Safety.      | (b) (4), (b) (6)     | 07 Apr 2021 15:09:37 |
| User entered 'US'         | System               | 17 Mar 2021 14:14:05 |

**US3222220**

**Folder: SAE USA-US104-2021-MRNA-1273-P301000015**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:05:20**

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '5' | System | 26 Apr 2021 17:52:41 |
| User entered '4' | System | 15 Apr 2021 13:32:11 |
| User entered '3' | System | 14 Apr 2021 13:22:04 |
| User entered '2' | System | 07 Apr 2021 15:09:51 |
| User entered '1' | System | 17 Mar 2021 14:14:05 |

**US3222220**

**Folder: SAE USA-US104-2021-MRNA-1273-P301000015**

**Form: Safety Report Form (5)**

**Generated On: 09 Jun 2021 16:05:20**

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User                 | Time (GMT)           |
|----------------------------------|----------------------|----------------------|
| User signature succeeded.        | Bruce Rankin (b) (4) | 28 Apr 2021 22:12:59 |
| User entered '26/Apr/2021 13:52' | (b) (4)<br>System    | 26 Apr 2021 17:52:41 |

US3222220

Folder: SAE USA-US104-2021-MRNA-1273-P301000015

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 16:05:20

**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. | Bruce Rankin (b) (4) | 28 Apr 2021 22:12:59 |
| Reviewed for Safety.      | (b) (4)              |                      |
|                           | (b) (4), (b) (6)     | 26 Apr 2021 17:52:44 |
| User entered 'I'          | (b) (4), (b) (6)     | 26 Apr 2021 17:52:41 |
|                           |                      |                      |