

US3222013 (Prod: Accel Research Site - Avail - ERN-PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 16:03:07

All time stamps listed in this document are displayed in GMT

US3222013

Form: Participant Creation

Data signed: (b) (4) 16 Feb 2021 16:27:02

Generated On: 09 Jun 2021 16:03:07

[Participant ID](#)

US3222013

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

US3222013

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 16:27:04

Generated On: 09 Jun 2021 16:03:07

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

| | |
|--------------------------|-------------|
| Visit date (dd MMM yyyy) | 06 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 |
|------------|------|

US3222013

Folder: Screening

Form: Demographics

Data signed: (b) (4) 16 Feb 2021 16:27:04

Generated On: 09 Jun 2021 16:03:07

| | |
|---|--|
| Date of Birth (MMM yyyy) | (b) (6) 1952 |
| Age | 68 |
| Age Units | YEARS |
| Age (Derived) | 68 |
| Sex | Female <input type="radio"/> Male <input checked="" type="radio"/> |
| Ethnicity | Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> 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 |

US3222013

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 16 Feb 2021 16:27:04

Generated On: 09 Jun 2021 16:03:07

| | |
|---|--|
| Date of Informed Consent (<i>dd MMM yyyy</i>) | 6 AUG 2020 |
| Month and Year of Informed Consent (derived) | AUG 2020 |
| Year of Informed Consent (derived) | 2020 |
| Protocol Version | Amendment 1 <input checked="" type="radio"/> Amendment 2 <input type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/> |
| Was participant enrolled in the study? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| If No, indicate reason for screen fail | Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/> |
| If reason for screen fail is Other, specify | |
| Was this participant screened previously? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| If Yes, previous participant number | |
| Enrollment Trigger | 1 |

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 16 Feb 2021 16:27:04

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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) 16 Feb 2021 16:27:04

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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) 16 Feb 2021 16:27:04

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| | |
|---|--|
| Condition | HYPERCHOLESTEROLEMIA |
| Start date (dd MMM yyyy) | 01 JAN 1995 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) _____ | |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 1995 |
| Start Year (derived) | 1995 |
| Stop Month and Year (derived) | _____ |
| Stop Year (derived) | _____ |

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 16 Feb 2021 16:27:04

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| | |
|---|--|
| Condition | ATRIAL FIBRILLATION |
| Start date (dd MMM yyyy) | 01 JAN 2019 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) | |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 2019 |
| Start Year (derived) | 2019 |
| Stop Month and Year (derived) | |
| Stop Year (derived) | |

US3222013

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 16 Feb 2021 16:27:04

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| | |
|---|--|
| Condition | MEMORY LOSS |
| Start date (dd MMM yyyy) | UN UNK 2020 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) _____ | |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 2020 |
| Start Year (derived) | 2020 |
| Stop Month and Year (derived) | _____ |
| Stop Year (derived) | _____ |

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 16 Feb 2021 16:27:04

Generated On: 09 Jun 2021 16:03:07

| | |
|---|--|
| Condition | SEASONAL ALLERGY |
| Start date (dd MMM yyyy) | UN UNK 2018 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) _____ | |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 2018 |
| Start Year (derived) | 2018 |
| Stop Month and Year (derived) | _____ |
| Stop Year (derived) | _____ |

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 16 Feb 2021 16:27:04

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

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 16 Feb 2021 16:27:04

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| | |
|---|--|
| Condition | OVERACTIVE BLADDER |
| Start date (dd MMM yyyy) | UN UNK 2018 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) | |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 2018 |
| Start Year (derived) | 2018 |
| Stop Month and Year (derived) | |
| Stop Year (derived) | |

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 16 Feb 2021 16:27:04

Generated On: 09 Jun 2021 16:03:07

| | |
|---|--------------------------------------|
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (<i>dd MMM yyyy</i>) | 6 AUG 2020 |
| Time of assessment (<i>00:00-23:59</i>) | 13:55 (24 HR) |
| Vital Signs Date and Time (derived) | 6 AUG 2020 13:55 |
| Height (<i>xxx.x</i>) | 172.7 cm |
| Weight (<i>xxx.x</i>) | 84.4 kg |
| BMI (<i>xxx.x</i>) | 28.29813 kg/m ² |
| 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) 16 Feb 2021 16:27:04

Generated On: 09 Jun 2021 16:03:07

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

6 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 16 Feb 2021 16:27:04

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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 ☐

Specify RETIRED

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 16 Feb 2021 16:27:04

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 16:27:04

Generated On: 09 Jun 2021 16:03:07

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 6 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 |

US3222013

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 16 Feb 2021 16:27:04

Generated On: 09 Jun 2021 16:03:07

What was the date of randomization? (dd MMM yyyy) 06 AUG 2020

What was the participant's randomization number? 184980

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 ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 16 Feb 2021 16:27:04

Generated On: 09 Jun 2021 16:03:07

| | |
|--------|---------------|
| 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) 16 Feb 2021 16:27:04

Generated On: 09 Jun 2021 16:03:07

| | |
|-------------------------------------|--|
| Height | ND - Not Done |
| Weight | ND - Not Done |
| 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) | 6 AUG 2020 |
| Time of assessment (00:00-23:59) | 13:55 (24 HR) |
| Vital Signs Date and Time (derived) | 6 AUG 2020 13:55 |
| Temperature (xxx.x) | 36.9 C |
| Route of measurement | Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 55 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 16 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 141 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 85 mmHg |
| Diastolic Blood Pressure units | MMHG |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Feb 2021 16:27:04

Generated On: 09 Jun 2021 16:03:07

| | |
|-------------------------------------|--|
| Height | ND - Not Done |
| Weight | ND - Not Done |
| Timepoint | Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/> |
| Were vital signs assessed? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 6 AUG 2020 |
| Time of assessment (00:00-23:59) | 15:17 (24 HR) |
| Vital Signs Date and Time (derived) | 6 AUG 2020 15:17 |
| Temperature (xxx.x) | 36.9 C |
| Route of measurement | Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 55 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 16 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 138 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 85 mmHg |
| Diastolic Blood Pressure units | MMHG |

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 16:27:04

Generated On: 09 Jun 2021 16:03:07

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

6 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) 16 Feb 2021 16:27:04

Generated On: 09 Jun 2021 16:03:07

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) 6 AUG 2020

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

Treatment Date and Time (derived) 6 AUG 2020 14:41

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 16:27:04

Generated On: 09 Jun 2021 16:03:07

| | |
|--|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (<i>dd MMM yyyy</i>) | 6 AUG 2020 |
| Collection time (<i>00:00-23:59</i>) | 14:03 (24 HR) |
| Collection date and time (derived) | 6 AUG 2020 14:03 |

US3222013

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 16 Feb 2021 16:27:04

Generated On: 09 Jun 2021 16:03:07

| | | | |
|-------------------------------|---------------------------|---------------------------------|------------------------------------|
| Collection date (dd MMM yyyy) | | | 6 AUG 2020 |
| Lab Test | Was the sample collected? | Collection time (00:00 - 23:59) | Collection date and time (derived) |
| Nasopharyngeal Swab 1 | Yes | 14:03 | 6 AUG 2020 14:03 |
| Nasopharyngeal Swab 2 | No | | |

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 16:27:04

Generated On: 09 Jun 2021 16:03:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

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

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 AUG 2020 15:10

PC Open Date & Time

06 AUG 2020 15:01

PC Close Date & Time

06 AUG 2020 17:31

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐
No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐
No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

06 AUG 2020 18:26

PC Close Date & Time

07 AUG 2020 11:59

US3222013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 AUG 2020 15:00

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3222013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 AUG 2020 15:02

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3222013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °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

09 AUG 2020 15:06

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3222013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:03:07

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

98.2 °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

10 AUG 2020 14:32

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3222013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:03:07

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

98.1 °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

11 AUG 2020 15:03

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3222013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:03:07

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

98.5 °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

12 AUG 2020 15:15

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3222013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

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

06 AUG 2020 15:11

PC Open Date & Time

06 AUG 2020 15:01

PC Close Date & Time

06 AUG 2020 17:31

US3222013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

06 AUG 2020 18:26

PC Close Date & Time

07 AUG 2020 11:59

US3222013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:03:07

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

3

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

07 AUG 2020 15:03

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3222013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:03:07

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

08 AUG 2020 15:02

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3222013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:03:07

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

09 AUG 2020 15:06

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3222013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:03:07

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

10 AUG 2020 14:32

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3222013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:03:07

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

11 AUG 2020 15:03

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3222013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:03:07

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

12 AUG 2020 15:15

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3222013

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

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 ☐

US3222013

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 06 AUG 2020 15:12 |
| PC Open Date & Time | 06 AUG 2020 15:01 |
| PC Close Date & Time | 06 AUG 2020 17:31 |

US3222013

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

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 ☐

US3222013

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

06 AUG 2020 18:26

PC Close Date & Time

07 AUG 2020 11:59

US3222013

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:03:07

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 ☒

US3222013

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:03:07

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 07 AUG 2020 15:04 |
| PC Open Date & Time | 07 AUG 2020 12:00 |
| PC Close Date & Time | 08 AUG 2020 11:59 |

US3222013

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3222013

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:03:07

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 08 AUG 2020 15:03 |
| PC Open Date & Time | 08 AUG 2020 12:00 |
| PC Close Date & Time | 09 AUG 2020 11:59 |

US3222013

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:03:07

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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US3222013

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:03:07

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 09 AUG 2020 15:07 |
| PC Open Date & Time | 09 AUG 2020 12:00 |
| PC Close Date & Time | 10 AUG 2020 11:59 |

US3222013

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:03:07

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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US3222013

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:03:07

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 10 AUG 2020 14:33 |
| PC Open Date & Time | 10 AUG 2020 12:00 |
| PC Close Date & Time | 11 AUG 2020 11:59 |

US3222013

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:03:07

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)

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US3222013

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:03:07

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 11 AUG 2020 15:04 |
| PC Open Date & Time | 11 AUG 2020 12:00 |
| PC Close Date & Time | 12 AUG 2020 11:59 |

US3222013

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:03:07

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)

57 of 1901

US3222013

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:03:07

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 12 AUG 2020 15:16 |
| PC Open Date & Time | 12 AUG 2020 12:00 |
| PC Close Date & Time | 13 AUG 2020 11:59 |

US3222013

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 16:27:04

Generated On: 09 Jun 2021 16:03:07

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222013

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 16:27:04

Generated On: 09 Jun 2021 16:03:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222013

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 13:33:59

Generated On: 09 Jun 2021 16:03:07

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222013

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 16:27:04

Generated On: 09 Jun 2021 16:03:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222013

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 13:33:59

Generated On: 09 Jun 2021 16:03:07

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222013

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 16:27:04

Generated On: 09 Jun 2021 16:03:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222013

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 16:27:05

Generated On: 09 Jun 2021 16:03:07

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 4 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 |

US3222013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Feb 2021 16:27:05

Generated On: 09 Jun 2021 16:03:07

| | |
|-------------------------------------|---|
| 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) | 4 SEP 2020 |
| Time of assessment (00:00-23:59) | 15:04 (24 HR) |
| Vital Signs Date and Time (derived) | 4 SEP 2020 15:04 |
| Temperature (xxx.x) | 36.8 C |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 57 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 16 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 150 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 87 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3222013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Feb 2021 16:27:05

Generated On: 09 Jun 2021 16:03:07

| | |
|-------------------------------------|---|
| 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) | 4 SEP 2020 |
| Time of assessment (00:00-23:59) | 16:12 (24 HR) |
| Vital Signs Date and Time (derived) | 4 SEP 2020 16:12 |
| Temperature (xxx.x) | 36.7 C |
| Route of measurement | Oral <input checked="" type="checkbox"/> |
| | Axillary <input type="checkbox"/> |
| | Other <input type="checkbox"/> |
| If Other, specify | |
| Pulse (xxx) | 60 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) | 70 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3222013

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 16:27:05

Generated On: 09 Jun 2021 16:03:07

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

4 SEP 2020

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

US3222013

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 16 Feb 2021 16:27:04

Generated On: 09 Jun 2021 16:03:07

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) 4 SEP 2020

What was the treatment time? (00:00-23:59) 15:37 (24 HR)

Treatment Date and Time (derived) 4 SEP 2020 15:37

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

US3222013

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 16:27:05

Generated On: 09 Jun 2021 16:03:07

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

4 SEP 2020

Collection time (00:00-23:59)

15:20 (24 HR)

Collection date and time (derived)

4 SEP 2020 15:20

US3222013

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 16 Feb 2021 16:27:04

Generated On: 09 Jun 2021 16:03:07

| | | | |
|-------------------------------|---------------------------|---------------------------------|------------------------------------|
| Collection date (dd MMM yyyy) | | | 4 SEP 2020 |
| Lab Test | Was the sample collected? | Collection time (00:00 - 23:59) | Collection date and time (derived) |
| Nasopharyngeal Swab 1 | Yes | 15:28 | 4 SEP 2020 15:28 |
| Nasopharyngeal Swab 2 | No | | |

US3222013

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 16:27:04

Generated On: 09 Jun 2021 16:03:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

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

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 SEP 2020 16:11

PC Open Date & Time

04 SEP 2020 15:57

PC Close Date & Time

04 SEP 2020 18:27

US3222013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.1 °F

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

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

| | |
|----------------------|-------------------|
| PC Time Stamp | 04 SEP 2020 20:28 |
| PC Open Date & Time | 04 SEP 2020 19:22 |
| PC Close Date & Time | 05 SEP 2020 11:59 |

US3222013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:03:07

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

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 SEP 2020 15:01

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3222013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °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

06 SEP 2020 14:57

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3222013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:03:07

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

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 SEP 2020 15:04

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3222013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:03:07

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

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 SEP 2020 14:46

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3222013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.9 °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

09 SEP 2020 14:37

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3222013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:03:07

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

98.5 °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

10 SEP 2020 15:02

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3222013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

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

04 SEP 2020 16:14

PC Open Date & Time

04 SEP 2020 15:57

PC Close Date & Time

04 SEP 2020 18:27

US3222013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

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

04 SEP 2020 20:29

PC Open Date & Time

04 SEP 2020 19:22

PC Close Date & Time

05 SEP 2020 11:59

US3222013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:03:07

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

05 SEP 2020 15:02

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3222013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:03:07

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

06 SEP 2020 14:58

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3222013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:03:07

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

07 SEP 2020 15:04

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3222013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:03:07

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

08 SEP 2020 14:47

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3222013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:03:07

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

09 SEP 2020 14:38

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3222013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:03:07

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

10 SEP 2020 15:02

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3222013

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

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 ☐

US3222013

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 04 SEP 2020 17:13 |
| PC Open Date & Time | 04 SEP 2020 15:57 |
| PC Close Date & Time | 04 SEP 2020 18:27 |

US3222013

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

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 ☐

US3222013

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 04 SEP 2020 20:30 |
| PC Open Date & Time | 04 SEP 2020 19:22 |
| PC Close Date & Time | 05 SEP 2020 11:59 |

US3222013

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:03:07

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)

US3222013

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:03:07

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 05 SEP 2020 15:03 |
| PC Open Date & Time | 05 SEP 2020 12:00 |
| PC Close Date & Time | 06 SEP 2020 11:59 |

US3222013

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:03:07

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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US3222013

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:03:07

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 06 SEP 2020 14:58 |
| PC Open Date & Time | 06 SEP 2020 12:00 |
| PC Close Date & Time | 07 SEP 2020 11:59 |

US3222013

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:03:07

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

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EAB) (1725)

US3222013

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:03:07

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 07 SEP 2020 15:05 |
| PC Open Date & Time | 07 SEP 2020 12:00 |
| PC Close Date & Time | 08 SEP 2020 11:59 |

US3222013

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:03:07

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 ☒

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EAB) (1725)

US3222013

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:03:07

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 08 SEP 2020 14:48 |
| PC Open Date & Time | 08 SEP 2020 12:00 |
| PC Close Date & Time | 09 SEP 2020 11:59 |

US3222013

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:03:07

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)

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US3222013

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:03:07

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 09 SEP 2020 14:38 |
| PC Open Date & Time | 09 SEP 2020 12:00 |
| PC Close Date & Time | 10 SEP 2020 11:59 |

US3222013

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:03:07

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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EAB) (1725)

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US3222013

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:03:07

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 10 SEP 2020 15:03 |
| PC Open Date & Time | 10 SEP 2020 12:00 |
| PC Close Date & Time | 11 SEP 2020 11:59 |

US3222013

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 16:27:04

Generated On: 09 Jun 2021 16:03:07

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222013

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 16:27:04

Generated On: 09 Jun 2021 16:03:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222013

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 16:27:04

Generated On: 09 Jun 2021 16:03:07

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222013

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 16:27:04

Generated On: 09 Jun 2021 16:03:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222013

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 16:27:04

Generated On: 09 Jun 2021 16:03:07

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222013

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 16:27:04

Generated On: 09 Jun 2021 16:03:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222013

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 16:27:05

Generated On: 09 Jun 2021 16:03:07

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 2 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 |

US3222013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Feb 2021 16:27:05

Generated On: 09 Jun 2021 16:03:07

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) _____

US3222013

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 16:27:05

Generated On: 09 Jun 2021 16:03:07

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.

US3222013

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 16:27:05

Generated On: 09 Jun 2021 16:03:07

| | |
|------------------------------------|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (dd MMM yyyy) | 2 OCT 2020 |
| Collection time (00:00-23:59) | 12:55 (24 HR) |
| Collection date and time (derived) | 2 OCT 2020 12:55 |

US3222013

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 16:27:05

Generated On: 09 Jun 2021 16:03:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

| 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"/> 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"/> 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"/> 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"/> Yes <input type="radio"/> |

US3222013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

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

Date and time of submission

Patient Cloud Open Date & Time

06 OCT 2020 00:01

Patient Cloud Close Date & Time

10 OCT 2020 23:59

US3222013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

| 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 <input type="radio"/> 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"/> 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"/> 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"/> Yes <input type="radio"/> |

US3222013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

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

Date and time of submission

Patient Cloud Open Date & Time

13 OCT 2020 00:01

Patient Cloud Close Date & Time

17 OCT 2020 23:59

US3222013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 OCT 2020 09:50:52

Patient Cloud Open Date & Time

20 OCT 2020 00:01

Patient Cloud Close Date & Time

24 OCT 2020 23:59

US3222013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

| 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 checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 03 NOV 2020 10:06:42 |
| Patient Cloud Open Date & Time | 03 NOV 2020 00:01 |
| Patient Cloud Close Date & Time | 07 NOV 2020 23:59 |

US3222013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

DAY 99

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 NOV 2020 09:07:58

Patient Cloud Open Date & Time

10 NOV 2020 00:01

Patient Cloud Close Date & Time

14 NOV 2020 23:59

US3222013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

| TIMEPOINT | DAY 106 |
|---|--|
| Have you 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"/> Yes <input checked="" type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input checked="" type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/> |
| Date and time of submission | 17 NOV 2020 08:32:21 |
| Patient Cloud Open Date & Time | 17 NOV 2020 00:01 |
| Patient Cloud Close Date & Time | 21 NOV 2020 23:59 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 | 21 NOV 2020 00:01 |
| Patient Cloud Close Date & Time | 25 NOV 2020 23:59 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 DEC 2020 10:19:46

Patient Cloud Open Date & Time

28 NOV 2020 00:01

Patient Cloud Close Date & Time

02 DEC 2020 23:59

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

| 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 checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 05 DEC 2020 12:05:21 |
| Patient Cloud Open Date & Time | 05 DEC 2020 00:01 |
| Patient Cloud Close Date & Time | 09 DEC 2020 23:59 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

| 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"/> 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"/> 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"/> 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"/> Yes <input type="radio"/> |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 | 12 DEC 2020 00:01 |
| Patient Cloud Close Date & Time | 16 DEC 2020 23:59 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

| TIMEPOINT | DAY 138 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> 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"/> 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"/> 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"/> Yes <input type="checkbox"/> |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

19 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

23 DEC 2020 23:59

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

| TIMEPOINT | DAY 145 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> 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"/> 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"/> 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"/> Yes <input type="checkbox"/> |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 | 26 DEC 2020 00:01 |
|--|-------------------|

| | |
|---|-------------------|
| Patient Cloud Close Date & Time | 30 DEC 2020 23:59 |
|---|-------------------|

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 JAN 2021 11:43:13

Patient Cloud Open Date & Time

02 JAN 2021 00:01

Patient Cloud Close Date & Time

06 JAN 2021 23:59

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 JAN 2021 10:39:41

Patient Cloud Open Date & Time

09 JAN 2021 00:01

Patient Cloud Close Date & Time

13 JAN 2021 23:59

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

| | |
|---|--|
| 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 checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 16 JAN 2021 10:17:33 |
| Patient Cloud Open Date & Time | 16 JAN 2021 00:01 |
| Patient Cloud Close Date & Time | 20 JAN 2021 23:59 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 JAN 2021 09:20:03

Patient Cloud Open Date & Time

23 JAN 2021 00:01

Patient Cloud Close Date & Time

27 JAN 2021 23:59

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

[Patient Cloud Close Date & Time](#)

03 FEB 2021 23:59

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

DAY 187

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

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

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

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 | 06 FEB 2021 00:01 |
| Patient Cloud Close Date & Time | 10 FEB 2021 23:59 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 FEB 2021 09:26:38

Patient Cloud Open Date & Time

13 FEB 2021 00:01

Patient Cloud Close Date & Time

17 FEB 2021 23:59

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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 ☒

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

20 FEB 2021 09:00:25

Patient Cloud Open Date & Time

20 FEB 2021 00:01

Patient Cloud Close Date & Time

24 FEB 2021 23:59

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 FEB 2021 08:38:25

Patient Cloud Open Date & Time

27 FEB 2021 00:01

Patient Cloud Close Date & Time

03 MAR 2021 23:59

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 MAR 2021 12:57:08

Patient Cloud Open Date & Time

06 MAR 2021 00:01

Patient Cloud Close Date & Time

10 MAR 2021 23:59

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 MAR 2021 12:58:29

Patient Cloud Open Date & Time

13 MAR 2021 00:01

Patient Cloud Close Date & Time

17 MAR 2021 23:59

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 MAR 2021 13:32:26

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

| | |
|---|--|
| 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 checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 27 MAR 2021 10:41:55 |
| Patient Cloud Open Date & Time | 27 MAR 2021 00:01 |
| Patient Cloud Close Date & Time | 31 MAR 2021 23:59 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

| | |
|---|--|
| 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 checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 03 APR 2021 12:20:23 |
| Patient Cloud Open Date & Time | 03 APR 2021 00:01 |
| Patient Cloud Close Date & Time | 07 APR 2021 23:59 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

Date and time of submission

10 APR 2021 08:14:27

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

Date and time of submission

17 APR 2021 17:37:49

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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 ☐

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

24 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

28 APR 2021 23:59

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

Date and time of submission

01 MAY 2021 09:13:21

Patient Cloud Open Date & Time

01 MAY 2021 00:01

Patient Cloud Close Date & Time

05 MAY 2021 23:59

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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 ☐

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

08 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 | 15 MAY 2021 00:01 |
| Patient Cloud Close Date & Time | 19 MAY 2021 23:59 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

22 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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 ☐ 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 ☐

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

29 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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 ☐

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 | 05 JUN 2021 00:01 |
| Patient Cloud Close Date & Time | 09 JUN 2021 23:59 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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 ☐

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

12 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

| TIMEPOINT | DAY 320 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> 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"/> 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"/> 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"/> Yes <input type="radio"/> |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

19 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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 ☐

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

26 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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 ☐

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 | 03 JUL 2021 00:01 |
| Patient Cloud Close Date & Time | 07 JUL 2021 23:59 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 | 10 JUL 2021 00:01 |
| Patient Cloud Close Date & Time | 14 JUL 2021 23:59 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 | 17 JUL 2021 00:01 |
| Patient Cloud Close Date & Time | 21 JUL 2021 23:59 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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 ☐

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 | 24 JUL 2021 00:01 |
|--|-------------------|

| | |
|---|-------------------|
| Patient Cloud Close Date & Time | 28 JUL 2021 23:59 |
|---|-------------------|

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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 ☐

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 | 31 JUL 2021 00:01 |
| Patient Cloud Close Date & Time | 04 AUG 2021 23:59 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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 ☐

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

07 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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 ☐

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 | 14 AUG 2021 00:01 |
| Patient Cloud Close Date & Time | 18 AUG 2021 23:59 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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 ☐

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

21 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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 ☐

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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 ☐

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 | 04 SEP 2021 00:01 |
| Patient Cloud Close Date & Time | 08 SEP 2021 23:59 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 | 11 SEP 2021 00:01 |
| Patient Cloud Close Date & Time | 15 SEP 2021 23:59 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

18 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

| TIMEPOINT | DAY 418 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> 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"/> 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"/> 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"/> Yes <input type="checkbox"/> |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 | 25 SEP 2021 00:01 |
| Patient Cloud Close Date & Time | 29 SEP 2021 23:59 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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 ☐

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 | 02 OCT 2021 00:01 |
|--|-------------------|

| | |
|---|-------------------|
| Patient Cloud Close Date & Time | 06 OCT 2021 23:59 |
|---|-------------------|

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

| TIMEPOINT | DAY 432 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> 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"/> 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"/> 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"/> Yes <input type="checkbox"/> |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

09 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

DAY 439

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

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

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

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

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

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

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

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

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2021 00:01 |
| Patient Cloud Close Date & Time | 20 OCT 2021 23:59 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 | 23 OCT 2021 00:01 |
| Patient Cloud Close Date & Time | 27 OCT 2021 23:59 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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 ☐

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

30 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

06 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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 ☐

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 | 13 NOV 2021 00:01 |
| Patient Cloud Close Date & Time | 17 NOV 2021 23:59 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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 ☐

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 | 04 DEC 2021 00:01 |
| Patient Cloud Close Date & Time | 08 DEC 2021 23:59 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

| TIMEPOINT | DAY 495 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> 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"/> 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"/> 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"/> Yes <input type="checkbox"/> |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 | 11 DEC 2021 00:01 |
| Patient Cloud Close Date & Time | 15 DEC 2021 23:59 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

DAY 502

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

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

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

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

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

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

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

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

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 | 18 DEC 2021 00:01 |
| Patient Cloud Close Date & Time | 22 DEC 2021 23:59 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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 ☐

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 | 25 DEC 2021 00:01 |
| Patient Cloud Close Date & Time | 29 DEC 2021 23:59 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

DAY 516

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

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

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

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

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

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

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

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

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

01 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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 ☐

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

08 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

| TIMEPOINT | DAY 530 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> 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"/> 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"/> 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"/> Yes <input type="checkbox"/> |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

15 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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 ☐

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 | 22 JAN 2022 00:01 |
| Patient Cloud Close Date & Time | 26 JAN 2022 23:59 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

| TIMEPOINT | DAY 544 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> 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"/> 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"/> 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"/> Yes <input type="checkbox"/> |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 | 29 JAN 2022 00:01 |
| Patient Cloud Close Date & Time | 02 FEB 2022 23:59 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

DAY 551

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

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

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

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

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

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

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

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

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 | 05 FEB 2022 00:01 |
| Patient Cloud Close Date & Time | 09 FEB 2022 23:59 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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 ☐

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 | 12 FEB 2022 00:01 |
| Patient Cloud Close Date & Time | 16 FEB 2022 23:59 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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°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 ☐

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

19 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

DAY 572

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

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

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

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

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

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

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

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

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

26 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

DAY 579

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

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

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

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

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

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

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

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

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

05 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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 ☐

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

12 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAR 2022 23:59

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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 ☐

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

19 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 | 26 MAR 2022 00:01 |
| Patient Cloud Close Date & Time | 30 MAR 2022 23:59 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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 ☐
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 ☐

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

02 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

06 APR 2022 23:59

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

09 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 APR 2022 23:59

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

| TIMEPOINT | DAY 621 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> 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"/> 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"/> 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"/> Yes <input type="checkbox"/> |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 APR 2022 00:01 |
| Patient Cloud Close Date & Time | 20 APR 2022 23:59 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

| TIMEPOINT | DAY 628 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> 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"/> 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"/> 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"/> Yes <input type="checkbox"/> |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 | 23 APR 2022 00:01 |
| Patient Cloud Close Date & Time | 27 APR 2022 23:59 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

| TIMEPOINT | DAY 635 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> 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"/> 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"/> 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"/> Yes <input type="radio"/> |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

30 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

DAY 642

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

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

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

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

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

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

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

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

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

07 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

14 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

| TIMEPOINT | DAY 656 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> 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"/> 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"/> 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"/> Yes <input type="checkbox"/> |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

21 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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 ☐

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

| TIMEPOINT | DAY 670 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> 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"/> 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"/> 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"/> Yes <input type="checkbox"/> |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

04 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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 ☐

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 | 11 JUN 2022 00:01 |
| Patient Cloud Close Date & Time | 15 JUN 2022 23:59 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 | 18 JUN 2022 00:01 |
| Patient Cloud Close Date & Time | 22 JUN 2022 23:59 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

| TIMEPOINT | DAY 691 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> 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"/> 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"/> 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"/> Yes <input type="checkbox"/> |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

25 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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 ☐

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 | |
| Patient Cloud Open Date & Time | 09 JUL 2022 00:01 |
| Patient Cloud Close Date & Time | 13 JUL 2022 23:59 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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 ☐
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 ☐

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUL 2022 00:01 |
| Patient Cloud Close Date & Time | 20 JUL 2022 23:59 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

23 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2022 23:59

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

30 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

| TIMEPOINT | DAY 733 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> 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"/> 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"/> 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"/> Yes <input type="checkbox"/> |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

06 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 | 13 AUG 2022 00:01 |
|--|-------------------|

| | |
|---|-------------------|
| Patient Cloud Close Date & Time | 17 AUG 2022 23:59 |
|---|-------------------|

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

| TIMEPOINT | DAY 747 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> 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"/> 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"/> 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"/> Yes <input type="checkbox"/> |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

20 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2022 23:59

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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 ☐

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 | 27 AUG 2022 00:01 |
| Patient Cloud Close Date & Time | 31 AUG 2022 23:59 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

DAY 761

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

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

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

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

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

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

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

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

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 | 03 SEP 2022 00:01 |
| Patient Cloud Close Date & Time | 07 SEP 2022 23:59 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 | 10 SEP 2022 00:01 |
| Patient Cloud Close Date & Time | 14 SEP 2022 23:59 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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 ☐

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

17 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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 ☐

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 | 24 SEP 2022 00:01 |
| Patient Cloud Close Date & Time | 28 SEP 2022 23:59 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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 ☐

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 | 01 OCT 2022 00:01 |
| Patient Cloud Close Date & Time | 05 OCT 2022 23:59 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

| TIMEPOINT | DAY 796 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> 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"/> 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"/> 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"/> Yes <input type="checkbox"/> |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

08 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2022 23:59

US3222013

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 16:03:07

| Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other? | Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache? | Date & Time of Submission |
|---|--|---------------------------|
| No | | 27 FEB 2021 08:38:38 |

US3222013

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 16:27:04

Generated On: 09 Jun 2021 16:03:07

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 28 OCT 2020

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

Comments 3 ATTEMPTS MADE WITH NO
RETURN CALLS

If Contact Not Made, please provide Comments

US3222013

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 16:27:04

Generated On: 09 Jun 2021 16:03:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222013

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 16:27:04

Generated On: 09 Jun 2021 16:03:07

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222013

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 16:27:04

Generated On: 09 Jun 2021 16:03:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222013

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 16:27:04

Generated On: 09 Jun 2021 16:03:07

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222013

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 16:27:04

Generated On: 09 Jun 2021 16:03:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222013

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 16:27:04

Generated On: 09 Jun 2021 16:03:07

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

01 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222013

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 25 Mar 2021 17:10:23

Generated On: 09 Jun 2021 16:03:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222013

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 25 Mar 2021 17:10:23

Generated On: 09 Jun 2021 16:03:07

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

| | |
|--------------------------|-------------|
| Visit date (dd MMM yyyy) | 16 MAR 2021 |
|--------------------------|-------------|

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

| | |
|------------|--------|
| Folder OID | VISIT4 |
|------------|--------|

US3222013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 20:10:01

Generated On: 09 Jun 2021 16:03:07

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) _____

US3222013

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 25 Mar 2021 17:10:23

Generated On: 09 Jun 2021 16:03:07

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 MAR 2021

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

US3222013

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 25 Mar 2021 17:10:23

Generated On: 09 Jun 2021 16:03:07

| | |
|------------------------------------|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (dd MMM yyyy) | 16 MAR 2021 |
| Collection time (00:00-23:59) | 14:02 (24 HR) |
| Collection date and time (derived) | 16 MAR 2021 14:02 |

US3222013

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 25 Mar 2021 17:10:23

Generated On: 09 Jun 2021 16:03:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222013

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 20:10:01

Generated On: 09 Jun 2021 16:03:07

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222013

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 20:10:01

Generated On: 09 Jun 2021 16:03:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222013

Folder: Safety Call Day 269 (1)

Form: Safety Call

Data signed: (b) (4) 03 May 2021 15:52:48

Generated On: 09 Jun 2021 16:03:07

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222013

Folder: Safety Call Day 269 (1)

Form: Continuing

Data signed: (b) (4) 03 May 2021 15:52:47

Generated On: 09 Jun 2021 16:03:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222013

Folder: Safety Call Day 299 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:07

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

US3222013

Folder: Safety Call Day 299 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:07

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3222013

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:03:07

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

US3222013

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 16:03:07

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3222013

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

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 16:27:03

Generated On: 09 Jun 2021 16:03:07

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

| | |
|--------------------------|-------------|
| Visit date (dd MMM yyyy) | 18 JAN 2021 |
|--------------------------|-------------|

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

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

US3222013

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

Form: Unblinding

Data signed: (b) (4) 25 Mar 2021 17:10:23

Generated On: 09 Jun 2021 16:03:07

Date of updated informed consent (*dd MMM yyyy*) 18 JAN 2021

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

Was the participant unblinded? Yes ☒ No ☐

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

Date of unblinding (*dd MMM yyyy*) 18 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

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

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

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3222013

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 16:27:03

Generated On: 09 Jun 2021 16:03:07

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

18 JAN 2021

Collection time (00:00-23:59)

14:00 (24 HR)

Collection date and time (derived)

18 JAN 2021 14:00

US3222013

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 16 Feb 2021 16:27:03

Generated On: 09 Jun 2021 16:03:07

| | |
|------------------------------------|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (dd MMM yyyy) | 18 JAN 2021 |
| Collection time (00:00 - 23:59) | 14:05 |
| Collection Date and Time (derived) | 18 JAN 2021 14:05 |

US3222013

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 16 Feb 2021 16:27:03

Generated On: 09 Jun 2021 16:03:07

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3222013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:07

| | |
|--|--|
| AEID | USA-US104-2020-MRNA-1273-P30 1000018 |
| Adverse event | ATRIAL FIBRILLATION - WORSENING |
| Was this a medically-attended AE? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Was this a Solicited Adverse Reaction? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Is this event a confirmed diagnosis of Symptomatic Covid-19? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Start date (dd MMM yyyy) | 14 NOV 2020 |
| Start time (00:00-23:59) | |
| AE start date and time (derived) | |
| Ongoing? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| If not Ongoing, end date (dd MMM yyyy) | 16 NOV 2020 |
| End time (00:00-23:59) | |
| AE End Date and Time (derived) | |
| Severity | Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/> |
| Is the adverse event serious? | Yes <input checked="" type="radio"/> 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) | 14 NOV 2020 |
| Hospital Discharge Date (dd MMM yyyy) | 16 NOV 2020 |
| Admitted to ICU? | Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/> |
| Number of Days in ICU | |
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US3222013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:07

| | |
|--|---|
| 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"/> Related <input type="radio"/> Not Applicable <input type="radio"/> |
| Relationship to Study Procedure | Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/> |
| Action taken with investigational product | None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> 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"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/> |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: | |
| Narrative | I WAS INFORMED OF THE SAE AT 11 AM ON 17/NOV/2020. I SPOKE WITH THE WIFE TODAY AND SHE SAID HE NORMALLY GOES TO THE HOSPITAL ONCE OR TWICE A YEAR FOR A-FIB ISSUES. HE HAS FULLY RECOVERED. I REQUESTED MEDICAL RECORDS. |

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EAB) (1725)

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US3222013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:07

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

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 16 Feb 2021 16:27:03

Generated On: 09 Jun 2021 16:03:07

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

Yes ☒

No ☐

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

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 16 Feb 2021 16:27:03

Generated On: 09 Jun 2021 16:03:07

Name of Medication DONEPEZIL

Prophylaxis Yes ☐
No ☒

Indication MEMORY LOSS

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 16 Feb 2021 16:27:03

Generated On: 09 Jun 2021 16:03:07

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

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 16 Feb 2021 16:27:03

Generated On: 09 Jun 2021 16:03:07

Name of Medication FENOFIBRATE

Prophylaxis Yes ☐
No ☒

Indication HYPERCHOLESTEROLEMIA

Dose per administration 54

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 16 Feb 2021 16:27:03

Generated On: 09 Jun 2021 16:03:07

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

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 16 Feb 2021 16:27:03

Generated On: 09 Jun 2021 16:03:07

Name of Medication LOVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERCHOLESTEROLEMIA

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 16 Feb 2021 16:27:03

Generated On: 09 Jun 2021 16:03:07

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

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 16 Feb 2021 16:27:03

Generated On: 09 Jun 2021 16:03:07

Name of Medication METROPOLOL

Prophylaxis Yes ☐
No ☒

Indication ATRIAL FIBRILLATION

Dose per administration 12.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 16 Feb 2021 16:27:03

Generated On: 09 Jun 2021 16:03:07

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

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 16 Feb 2021 16:27:03

Generated On: 09 Jun 2021 16:03:07

Name of Medication MONTELUKAST

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGY

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 16 Feb 2021 16:27:03

Generated On: 09 Jun 2021 16:03:07

| | | |
|--|--------------------------|----------------------------------|
| | 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 2018 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | 1 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 16 Feb 2021 16:27:03

Generated On: 09 Jun 2021 16:03:07

Name of Medication OMEPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication GERD

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 16 Feb 2021 16:27:03

Generated On: 09 Jun 2021 16:03:07

| | | |
|--|--------------------------|----------------------------------|
| | 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 2010 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | 1 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 16 Feb 2021 16:27:03

Generated On: 09 Jun 2021 16:03:07

Name of Medication TAMSULOSIN

Prophylaxis Yes ☐
No ☒

Indication OVERACTIVE BLADDER

Dose per administration 0.4

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

348 of 1901

EAB) (1725)

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 16 Feb 2021 16:27:03

Generated On: 09 Jun 2021 16:03:07

| | | |
|--|--------------------------|----------------------------------|
| | 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 2018 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | 2 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 16 Feb 2021 16:27:03

Generated On: 09 Jun 2021 16:03:07

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication SEASONAL INFLUENZA

Dose per administration 1

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

If dose unit is Other, specify INJECTION

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)

350 of 1901

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 16 Feb 2021 16:27:03

Generated On: 09 Jun 2021 16:03:07

| | | |
|--|--------------------------|----------------------------------|
| | Intramuscular | <input checked="" type="radio"/> |
| | Respiratory (Inhalation) | <input type="radio"/> |
| | Intralesional | <input type="radio"/> |
| | Intraperitoneal | <input type="radio"/> |
| | Nasal | <input type="radio"/> |
| | Vaginal | <input type="radio"/> |
| | Rectal | <input type="radio"/> |
| | Intravenous | <input type="radio"/> |
| | Intravenous Bolus | <input type="radio"/> |
| | Intravenous Drip | <input type="radio"/> |
| | Other | <input type="radio"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | | 16 SEP 2020 |
| Start date completely unknown | | False |
| Ongoing? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) | | 16 SEP 2020 |
| 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"/> |

US3222013

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 16 Feb 2021 16:27:03

Generated On: 09 Jun 2021 16:03:07

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3222013

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 16:03:07

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

US3222013

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:03:07

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 ☐

US3222013

Folder: SAE USA-US104-2020-MRNA-1273-P301000018

Form: Safety Report Form

Data signed: (b) (4) 16 Feb 2021 16:27:03

Generated On: 09 Jun 2021 16:03:07

| | |
|--|--|
| SAEID | USA-US104-2020-MRNA-1273-P301000018 |
| Serious | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Persistent or significant disability or incapacity | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Investigator's First Name | TERESA |
| Investigator's Last Name | BECKER |
| Site Address: Street | 6550 MAPLERIDGE STREET |
| Site Address: City | HOUSTON |
| Site Address: State | |
| Site Address: Postal Code | 77081 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 3 |

US3222013

Folder: SAE USA-US104-2020-MRNA-1273-P301000018

Form: Safety Report Form (1)

Data signed: (b) (4) 16 Feb 2021 16:27:03

Generated On: 09 Jun 2021 16:03:07

| | |
|---|--|
| SAEID | USA-US104-2020-MRNA-1273-P301000018 |
| Serious | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Persistent or significant disability or incapacity | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Investigator's First Name | TERESA |
| Investigator's Last Name | BECKER |
| Site Address: Street | 6550 MAPLERIDGE STREET |
| Site Address: City | HOUSTON |
| Site Address: State | |
| Site Address: Postal Code | 77081 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 3 |
| Date of submission (Pre-filled from custom function) | 18/NOV/2020 20:39 |
| Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge. | True |

US3222013

Folder: SAE USA-US104-2020-MRNA-1273-P301000018

Form: Safety Report Form (2)

Data signed: (b) (4) 16 Feb 2021 16:27:03

Generated On: 09 Jun 2021 16:03:07

| | |
|---|--|
| SAEID | USA-US104-2020-MRNA-1273-P301000018 |
| Serious | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Persistent or significant disability or incapacity | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Investigator's First Name | TERESA |
| Investigator's Last Name | BECKER |
| Site Address: Street | 6550 MAPLERIDGE STREET |
| Site Address: City | HOUSTON |
| Site Address: State | |
| Site Address: Postal Code | 77081 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 3 |
| Date of submission (Pre-filled from custom function) | 03/DEC/2020 11:51 |
| 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 |

US3222013

Folder: SAE USA-US104-2020-MRNA-1273-P301000018

Form: Safety Report Form (3)

Data signed: (b) (4) 16 Feb 2021 16:27:03

Generated On: 09 Jun 2021 16:03:07

| | |
|---|--|
| SAEID | USA-US104-2020-MRNA-1273-P301000018 |
| Serious | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Persistent or significant disability or incapacity | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Investigator's First Name | TERESA |
| Investigator's Last Name | BECKER |
| Site Address: Street | 6550 MAPLERIDGE STREET |
| Site Address: City | HOUSTON |
| Site Address: State | |
| Site Address: Postal Code | 77081 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 3 |
| Date of submission (Pre-filled from custom function) | 11/DEC/2020 12:31 |
| 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

US3222013 (Prod: Accel Research Site - Avail - ERN-PPDS)

US3222013

Form: Participant Creation

Generated On: 09 Jun 2021 16:03:07

[Participant ID](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'US3222013' | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 06 Aug 2020 17:49:30 |

US3222013

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:03:07

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'Yes (Y)' | Jennifer Dittman (b) (4) | 06 Aug 2020 18:20:21 |

US3222013

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered '06 AUG 2020' | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 06 Aug 2020 17:49:31 |

US3222013

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:03:07

[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 09:29:17 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'Clinic (Clinic)' | Jennifer Dittman (b) (4) | 06 Aug 2020 18:20:21 |

US3222013

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:03:07

[Folder OID](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User entered 'SCRN' | System | 06 Aug 2020 18:20:21 |

US3222013

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:03:07

Date of Birth (MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered (b) (6) 1952' | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 06 Aug 2020 17:49:32 |

US3222013

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:03:07

[Age](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered '68' | (b) (4) Amber Vasquez (b) (4) | 06 Aug 2020 19:22:57 |

US3222013

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:03:07

[Age Units](#)

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User entered 'YEARS' | System | 06 Aug 2020 19:22:57 |

US3222013

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:03:07

[Age \(Derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User entered '68' | System | 06 Aug 2020 18:20:33 |

US3222013

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:03:07

[Sex](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'Male (M)' | (b) (4) Amber Vasquez (b) (4) | 06 Aug 2020 19:22:57 |

US3222013

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:03:07

[Ethnicity](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)' | (b) (4) Amber Vasquez (b) (4) | 06 Aug 2020 19:22:57 |

US3222013

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:03:07

White

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'I' | Amber Vasquez (b) (4) | 06 Aug 2020 19:22:57 |

US3222013

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:03:07

Black

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered '0' | Amber Vasquez (b) (4) | 06 Aug 2020 19:22:57 |

US3222013

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:03:07

[Asian](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered '0' | Amber Vasquez (b) (4) | 06 Aug 2020 19:22:57 |

US3222013

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:03:07

[American Indian or Alaska Native](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered '0' | (b) (4) Amber Vasquez (b) (4) | 06 Aug 2020 19:22:57 |

US3222013

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:03:07

[Native Hawaiian or other Pacific Islander](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered '0' | (b) (4) Amber Vasquez (b) (4) | 06 Aug 2020 19:22:57 |

US3222013

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:03:07

[Other](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered '0' | Amber Vasquez (b) (4) | 06 Aug 2020 19:22:57 |

US3222013

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:03:07

If race is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered empty. | (b) (4) | |
| | Amber Vasquez (b) (4) | 06 Aug 2020 19:22:57 |
| | (b) (4) | |

US3222013

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:03:07

[Unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered '0' | Amber Vasquez (b) (4) | 06 Aug 2020 19:22:57 |

US3222013

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:03:07

Not reported

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered '0' | Amber Vasquez (b) (4) | 06 Aug 2020 19:22:57 |

US3222013

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:03:07

Date of Informed Consent (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Aug 2020 20:01:41 |
| User entered '6 Aug 2020' | Jennifer Dittman (b) (4) (b) (4) | 06 Aug 2020 18:20:33 |

US3222013

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User entered 'Aug 2020' | System | 06 Aug 2020 18:20:33 |

US3222013

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User entered '2020' | System | 06 Aug 2020 18:20:33 |

US3222013

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:03:07

[Protocol Version](#)

| Audit | User | Time (GMT) |
|--------------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Aug 2020 20:01:41 |
| User entered 'Amendment 1 (1)' | Jennifer Dittman (b) (4) (b) (4) | 06 Aug 2020 18:20:33 |

US3222013

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Aug 2020 20:01:41 |
| User entered 'Yes (Y)' | Jennifer Dittman (b) (4) (b) (4) | 06 Aug 2020 18:20:33 |

US3222013

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:03:07

If No, indicate reason for screen fail

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Aug 2020 20:01:41 |
| User entered empty. | Jennifer Dittman (b) (4) (b) (4) | 06 Aug 2020 18:20:33 |

US3222013

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:03:07

If reason for screen fail is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Aug 2020 20:01:41 |
| User entered empty. | Jennifer Dittman (b) (4) (b) (4) | 06 Aug 2020 18:20:33 |

US3222013

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:03:07

[Was this participant screened previously?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Aug 2020 20:01:41 |
| User entered 'No (N)' | Jennifer Dittman (b) (4) (b) (4) | 06 Aug 2020 18:20:33 |

US3222013

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:03:07

[If Yes, previous participant number](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Aug 2020 20:01:41 |
| User entered empty. | RWS_ENDPOINT ENDPOINT (b) (4) | 06 Aug 2020 17:49:31 |

US3222013

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:03:07

[Enrollment Trigger](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User entered 'I' | System | 06 Aug 2020 18:44:03 |

US3222013

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'Yes (Y)' | Jennifer Dittman (b) (4) | 06 Aug 2020 18:44:03 |

US3222013

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 16:03:07

[Were any significant conditions reported?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'Yes (Y)' | (b) (4) Amber Vasquez (b) (4) | 06 Aug 2020 19:23:35 |

US3222013

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:03:07

Condition

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0. | Coder Import (b) (4) | 06 Aug 2020 19:25:57 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 06 Aug 2020 19:25:57 |
| Data point term sent to Coder | System | 06 Aug 2020 19:25:03 |
| User entered 'Hypercholesterolemia' | Amber Vasquez (b) (4) | 06 Aug 2020 19:24:13 |

US3222013

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered '01 Jan 1995' | Amber Vasquez (b) (4) | 06 Aug 2020 19:24:13 |

US3222013

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:03:07

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered '0' | Amber Vasquez (b) (4) | 06 Aug 2020 19:24:13 |

US3222013

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:03:07

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'Yes (Y)' | Amber Vasquez (b) (4) | 06 Aug 2020 19:24:13 |

US3222013

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered empty. | Amber Vasquez (b) (4) | 06 Aug 2020 19:24:13 |

US3222013

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:03:07

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered '0' | Amber Vasquez (b) (4) | 06 Aug 2020 19:24:13 |

US3222013

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User entered 'Jan 1995' | System | 06 Aug 2020 19:24:13 |

US3222013

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User entered '1995' | System | 06 Aug 2020 19:24:13 |

US3222013

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User entered empty. | System | 06 Aug 2020 19:24:13 |

US3222013

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User entered empty. | System | 06 Aug 2020 19:24:13 |

Condition

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User closed query 'Per CDM: Response noted however please confirm date of related concomitant medication and provide update.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 20 Oct 2020 10:28:43 |
| Query 'Per CDM: Response noted however please confirm date of related concomitant medication and provide update.' answered with 'CORRECT AS ENTERED' (Site from DM). | Albert Garcia (b) (4) (b) (4) | 12 Oct 2020 14:00:41 |
| User opened query 'Per CDM: Response noted however please confirm date of related concomitant medication and provide update.' (Site from DM). | (b) (4), (b) (6) | 09 Oct 2020 19:45:48 |
| User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM). | (b) (4), (b) (6) | 09 Oct 2020 19:45:48 |
| Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' answered with 'Con Med updated.' (Site from DM). | Thais Truffa (b) (4) | 18 Sep 2020 16:25:34 |
| User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM). | (b) (4), (b) (6) | 10 Sep 2020 12:33:22 |
| User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial fibrillation, LLT: Atrial fibrillation - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 06 Aug 2020 19:27:00 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 06 Aug 2020 19:27:00 |
| Data point term sent to Coder | System | 06 Aug 2020 19:26:06 |
| User entered 'Atrial Fibrillation' | Amber Vasquez (b) (4) (b) (4) | 06 Aug 2020 19:25:07 |

US3222013

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered '01 Jan 2019' | Amber Vasquez (b) (4) | 06 Aug 2020 19:25:07 |

US3222013

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:03:07

Start date completely unknown

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered '0' | Amber Vasquez (b) (4) | 06 Aug 2020 19:25:07 |

US3222013

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:03:07

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'Yes (Y)' | (b) (4) Amber Vasquez (b) (4) | 06 Aug 2020 19:25:07 |

US3222013

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered empty. | Amber Vasquez (b) (4) | 06 Aug 2020 19:25:07 |

US3222013

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:03:07

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered '0' | Amber Vasquez (b) (4) | 06 Aug 2020 19:25:07 |

US3222013

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User entered 'Jan 2019' | System | 06 Aug 2020 19:25:07 |

US3222013

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User entered '2019' | System | 06 Aug 2020 19:25:07 |

US3222013

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User entered empty. | System | 06 Aug 2020 19:25:07 |

US3222013

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User entered empty. | System | 06 Aug 2020 19:25:07 |

US3222013

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:03:07

[Condition](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User coded data point as SOC: Nervous system disorders, HLGT: Mental impairment disorders, HLT: Memory loss (excl dementia), PT: Amnesia, LLT: Memory loss - version MedDRA\\23.0. | Coder Import (b) (4) | 31 Oct 2020 13:15:22 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 31 Oct 2020 13:15:22 |
| Data point term sent to Coder | System | 31 Oct 2020 13:14:30 |
| User entered 'MEMORY LOSS' | Albert Garcia (b) (4) | 31 Oct 2020 13:14:30 |

US3222013

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'UN UNK 2020' | Albert Garcia (b) (4) | 31 Oct 2020 13:14:30 |

US3222013

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:03:07

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered '0' | Albert Garcia (b) (4) | 31 Oct 2020 13:14:30 |

US3222013

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:03:07

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'Yes (Y)' | Albert Garcia (b) (4) | 31 Oct 2020 13:14:30 |

US3222013

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered empty. | Albert Garcia (b) (4) | 31 Oct 2020 13:14:30 |

US3222013

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:03:07

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered '0' | Albert Garcia (b) (4) | 31 Oct 2020 13:14:30 |

US3222013

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User entered 'Jan 2020' | System | 31 Oct 2020 13:14:30 |

US3222013

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User entered '2020' | System | 31 Oct 2020 13:14:30 |

US3222013

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User entered empty. | System | 31 Oct 2020 13:14:30 |

US3222013

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User entered empty. | System | 31 Oct 2020 13:14:30 |

US3222013

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:03:07

Condition

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0. | Coder Import (b) (4) | 31 Oct 2020 13:18:11 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 31 Oct 2020 13:18:11 |
| Data point term sent to Coder | System | 31 Oct 2020 13:17:31 |
| User entered 'SEASONAL ALLERGY' | Albert Garcia (b) (4) | 31 Oct 2020 13:16:57 |

US3222013

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'UN UNK 2018' | Albert Garcia (b) (4) | 31 Oct 2020 13:16:57 |

US3222013

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:03:07

Start date completely unknown

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered '0' | Albert Garcia (b) (4) | 31 Oct 2020 13:16:57 |

US3222013

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:03:07

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'Yes (Y)' | Albert Garcia (b) (4) | 31 Oct 2020 13:16:57 |

US3222013

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered empty. | Albert Garcia (b) (4) | 31 Oct 2020 13:16:57 |

US3222013

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:03:07

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered '0' | Albert Garcia (b) (4) | 31 Oct 2020 13:16:57 |

US3222013

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:03:07

Start Month and Year (derived)

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User entered 'Jan 2018' | System | 31 Oct 2020 13:16:57 |

US3222013

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:03:07

Start Year (derived)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User entered '2018' | System | 31 Oct 2020 13:16:57 |

US3222013

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User entered empty. | System | 31 Oct 2020 13:16:57 |

US3222013

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User entered empty. | System | 31 Oct 2020 13:16:57 |

US3222013

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:03:07

[Condition](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| 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) | 31 Oct 2020 13:18:11 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 31 Oct 2020 13:18:11 |
| Data point term sent to Coder | System | 31 Oct 2020 13:17:31 |
| User entered 'GERD' | Albert Garcia (b) (4) | 31 Oct 2020 13:17:09 |

US3222013

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'UN UNK 2010' | Albert Garcia (b) (4) | 31 Oct 2020 13:17:09 |

US3222013

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:03:07

Start date completely unknown

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered '0' | Albert Garcia (b) (4) | 31 Oct 2020 13:17:09 |

US3222013

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:03:07

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'Yes (Y)' | Albert Garcia (b) (4) | 31 Oct 2020 13:17:09 |

US3222013

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered empty. | Albert Garcia (b) (4) | 31 Oct 2020 13:17:09 |

US3222013

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:03:07

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered '0' | Albert Garcia (b) (4) | 31 Oct 2020 13:17:09 |

US3222013

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User entered 'Jan 2010' | System | 31 Oct 2020 13:17:09 |

US3222013

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User entered '2010' | System | 31 Oct 2020 13:17:09 |

US3222013

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User entered empty. | System | 31 Oct 2020 13:17:09 |

US3222013

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User entered empty. | System | 31 Oct 2020 13:17:09 |

US3222013

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:03:07

Condition

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User coded data point as SOC: Renal and urinary disorders, HLGT: Bladder and bladder neck disorders (excl calculi), HLT: Myoneurogenic bladder disorders, PT: Hypertonic bladder, LLT: Overactive bladder - version MedDRA\\23.0. | Coder Import (b) (4) | 31 Oct 2020 13:18:11 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 31 Oct 2020 13:18:11 |
| Data point term sent to Coder | System | 31 Oct 2020 13:17:31 |
| User entered 'OVERACTIVE BLADDER' | Albert Garcia (b) (4) | 31 Oct 2020 13:17:24 |

US3222013

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'UN UNK 2018' | Albert Garcia (b) (4) | 31 Oct 2020 13:17:24 |

US3222013

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:03:07

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered '0' | Albert Garcia (b) (4) | 31 Oct 2020 13:17:24 |

US3222013

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:03:07

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'Yes (Y)' | Albert Garcia (b) (4) | 31 Oct 2020 13:17:24 |

US3222013

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered empty. | Albert Garcia (b) (4) | 31 Oct 2020 13:17:24 |

US3222013

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:03:07

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered '0' | Albert Garcia (b) (4) | 31 Oct 2020 13:17:24 |

US3222013

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:03:07

Start Month and Year (derived)

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User entered 'Jan 2018' | System | 31 Oct 2020 13:17:24 |

US3222013

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:03:07

Start Year (derived)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User entered '2018' | System | 31 Oct 2020 13:17:24 |

US3222013

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User entered empty. | System | 31 Oct 2020 13:17:24 |

US3222013

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User entered empty. | System | 31 Oct 2020 13:17:24 |

US3222013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:07

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'Yes (Y)' | (b) (4) | |
| | Amber Vasquez (b) (4) | 06 Aug 2020 19:26:24 |
| | (b) (4) | |

US3222013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:07

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered '6 Aug 2020' | (b) (4) Amber Vasquez (b) (4) | 06 Aug 2020 19:26:24 |

US3222013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered '13:55' | (b) (4) | 06 Aug 2020 19:26:24 |
| | Amber Vasquez (b) (4) | |
| | (b) (4) | |

US3222013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User entered '6 Aug 2020 13:55' | System | 06 Aug 2020 19:26:24 |

US3222013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:07

Height (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered '172.7' cm | (b) (4) Amber Vasquez (b) (4) | 06 Aug 2020 19:26:24 |
| DataPoint set to visible. | (b) (4) System | 06 Aug 2020 18:44:03 |

US3222013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:07

Weight (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered '84.4' kg | (b) (4) | |
| | Amber Vasquez (b) (4) | 06 Aug 2020 19:26:24 |
| DataPoint set to visible. | (b) (4) | |
| | System | 06 Aug 2020 18:44:03 |

US3222013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:07

BMI (xxx.x)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| Amendment Manager: User entered '28.29813' | System | 16 Sep 2020 23:45:53 |
| User entered '28.3' | System | 06 Aug 2020 19:26:24 |
| DataPoint set to visible. | System | 06 Aug 2020 18:44:03 |

US3222013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:07

[BMI units](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User entered 'kg/m2' | System | 06 Aug 2020 19:26:24 |
| DataPoint set to visible. | System | 06 Aug 2020 18:44:03 |

US3222013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:07

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| 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) (b) (4), (b) (6) | 21 Sep 2020 16:04:35 |
| 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) (b) (4) | 15 Sep 2020 17:24:25 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Albert Garcia (b) (4) (b) (4) | 15 Sep 2020 17:24:09 |
| 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 10:48:39 |
| User entered '36.9' C | Amber Vasquez (b) (4) (b) (4) | 06 Aug 2020 19:26:24 |

US3222013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:07

[Route of measurement](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered empty; reason for change Data Entry Error | (b) (4) | |
| | Albert Garcia (b) (4) | 15 Sep 2020 17:24:09 |
| | (b) (4) | |
| User entered 'Oral (Oral)' | Amber Vasquez (b) (4) | 06 Aug 2020 19:26:24 |
| | (b) (4) | |

US3222013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:07

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered empty. | Amber Vasquez (b) (4) | 06 Aug 2020 19:26:24 |

US3222013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:07

Pulse (xxx)

| Audit | User | Time (GMT) |
|---|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| 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) (b) (4), (b) (6) | 21 Sep 2020 16:04:37 |
| 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) (b) (4) | 15 Sep 2020 17:24:38 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Albert Garcia (b) (4) (b) (4) | 15 Sep 2020 17:24:09 |
| 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 10:48:45 |
| User entered '55' | Amber Vasquez (b) (4) (b) (4) | 06 Aug 2020 19:26:24 |

US3222013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:07

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User entered 'bpm' | System | 06 Aug 2020 19:26:24 |

US3222013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|---|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| 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) (b) (4), (b) (6) | 21 Sep 2020 16:04:40 |
| 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) (b) (4) | 15 Sep 2020 17:24:54 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Albert Garcia (b) (4) (b) (4) | 15 Sep 2020 17:24:09 |
| 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 10:49:00 |
| User entered '16' | Amber Vasquez (b) (4) (b) (4) | 06 Aug 2020 19:26:24 |

US3222013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:07

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User entered 'breaths/min' | System | 06 Aug 2020 19:26:24 |

US3222013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:07

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| 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) (b) (4), (b) (6) | 21 Sep 2020 16:04:42 |
| 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) (b) (4) | 15 Sep 2020 17:25:10 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Albert Garcia (b) (4) (b) (4) | 15 Sep 2020 17:24:09 |
| 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 10:49:07 |
| User entered '141' | Amber Vasquez (b) (4) (b) (4) | 06 Aug 2020 19:26:24 |

US3222013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:07

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User entered 'mmHg' | System | 06 Aug 2020 19:26:24 |

US3222013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:07

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| 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) (b) (4), (b) (6) | 21 Sep 2020 16:04:45 |
| 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) (b) (4) | 15 Sep 2020 17:25:24 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Albert Garcia (b) (4) (b) (4) | 15 Sep 2020 17:24:09 |
| 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 10:49:12 |
| User entered '85' | Amber Vasquez (b) (4) (b) (4) | 06 Aug 2020 19:26:24 |

US3222013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:07

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User entered 'mmHg' | System | 06 Aug 2020 19:26:24 |

US3222013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:07

Height (derived)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |

US3222013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:07

Weight (derived)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| | | |

US3222013

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:03:07

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'Yes (Y)' | (b) (4) Amber Vasquez (b) (4) | 06 Aug 2020 19:26:35 |

US3222013

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:03:07

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System). | (b) (4) (b) (4), (b) (6) | 07 Sep 2020 10:27:04 |
| User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System). | System | 04 Sep 2020 19:54:49 |
| User entered '6 Aug 2020' | Amber Vasquez (b) (4) (b) (4) | 06 Aug 2020 19:26:35 |

US3222013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:03:07

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 09:29:17 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'No (N)' | Jennifer Dittman (b) (4) | 06 Aug 2020 18:44:36 |

US3222013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:03:07

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 09:29:17 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'No (N)' | Jennifer Dittman (b) (4) | 06 Aug 2020 18:44:36 |

US3222013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:03:07

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 09:29:17 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'No (N)' | Jennifer Dittman (b) (4) | 06 Aug 2020 18:44:36 |

US3222013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:03:07

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 09:29:17 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'No (N)' | Jennifer Dittman (b) (4) | 06 Aug 2020 18:44:36 |

US3222013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:03:07

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 09:29:17 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'No (N)' | Jennifer Dittman (b) (4) | 06 Aug 2020 18:44:36 |

US3222013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:03:07

[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 09:29:17 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'No (N)' | Jennifer Dittman (b) (4) | 06 Aug 2020 18:44:36 |

US3222013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:03:07

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 09:29:17 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'No (N)' | Jennifer Dittman (b) (4) | 06 Aug 2020 18:44:36 |

US3222013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:03:07

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 09:29:17 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'No (N)' | Jennifer Dittman (b) (4) | 06 Aug 2020 18:44:36 |

US3222013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:03:07

[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 09:29:17 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'No (N)' | Jennifer Dittman (b) (4) | 06 Aug 2020 18:44:36 |

US3222013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:03:07

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 09:29:17 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'No (N)' | Jennifer Dittman (b) (4) | 06 Aug 2020 18:44:36 |

US3222013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:03:07

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 09:29:17 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'No (N)' | Jennifer Dittman (b) (4) | 06 Aug 2020 18:44:36 |

US3222013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:03:07

Other

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'Yes (Y)' | Jennifer Dittman (b) (4) | 06 Aug 2020 18:44:36 |

US3222013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:03:07

[Specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'RETIRED' | Jennifer Dittman (b) (4) | 06 Aug 2020 18:44:36 |

US3222013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:03:07

No Risk Identified

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered '0' | Jennifer Dittman (b) (4) | 06 Aug 2020 18:44:36 |

US3222013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered '0' | Jennifer Dittman (b) (4) | 06 Aug 2020 18:44:36 |

US3222013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:03:07

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 09:29:17 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered '0' | Jennifer Dittman (b) (4) | 06 Aug 2020 18:44:36 |

US3222013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:03:07

[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 09:29:17 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered '0' | Jennifer Dittman (b) (4) | 06 Aug 2020 18:44:36 |

US3222013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:03:07

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 09:29:17 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered '0' | Jennifer Dittman (b) (4) | 06 Aug 2020 18:44:36 |

US3222013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'I' | Jennifer Dittman (b) (4) | 06 Aug 2020 18:44:36 |

US3222013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:03:07

Other

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered '0' | Jennifer Dittman (b) (4) | 06 Aug 2020 18:44:36 |

US3222013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:03:07

[Specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 09:29:17 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered empty. | Jennifer Dittman (b) (4) | 06 Aug 2020 18:44:36 |

US3222013

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:03:07

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:10:27 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'Yes (Y)' | Jennifer Dittman (b) (4) | 06 Aug 2020 18:44:49 |

US3222013

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:03:07

Visit date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:10:27 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered '6 Aug 2020' | Jennifer Dittman (b) (4) | 06 Aug 2020 18:44:49 |

US3222013

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|--------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:10:27 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'Clinic (Clinic)' | Jennifer Dittman (b) (4) | 06 Aug 2020 18:44:49 |

US3222013

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:03:07

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:10:27 |
| User entered 'VISIT1' | System | 06 Aug 2020 18:44:49 |

US3222013

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:10:27 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered '06 AUG 2020' | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 06 Aug 2020 18:09:42 |

US3222013

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:03:07

What was the participant's randomization number?

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:10:27 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System). | (b) (4) System | 21 Aug 2020 02:36:19 |
| Amendment Manager: Data point set to conformant. | System | 21 Aug 2020 02:36:19 |
| User opened query 'Data entered is non-conformant. Please correct.' (Site from System). | System | 06 Aug 2020 18:09:42 |
| User entered '184980' (non-conformant). | RWS_ENDPOINT ENDPOINT (b) (4) | 06 Aug 2020 18:09:42 |

US3222013

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|-------------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:10:27 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered '>=65 years (3)' | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 06 Aug 2020 18:09:42 |

US3222013

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:03:07

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) | 03 Apr 2021 15:10:27 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'No (N)' | Amber Vasquez (b) (4) | 06 Aug 2020 19:27:19 |

US3222013

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:03:07

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) | 03 Apr 2021 15:10:27 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Jennifer Dittman (b) (4) | 07 Aug 2020 22:17:31 |
| User entered 'No (N)' | Amber Vasquez (b) (4) | 06 Aug 2020 19:27:19 |

US3222013

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:10:27 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'No (N)' | (b) (4) Amber Vasquez (b) (4) | 06 Aug 2020 19:27:19 |

US3222013

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:03:07

Diabetes (Type I, Type 2, or gestational)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:10:27 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'No (N)' | (b) (4) Amber Vasquez (b) (4) | 06 Aug 2020 19:27:19 |

US3222013

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:03:07

[Liver Disease](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:10:27 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'No (N)' | (b) (4) Amber Vasquez (b) (4) | 06 Aug 2020 19:27:19 |

US3222013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:03:07

Height

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:10:27 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User closed query 'Per CDM: Thanks for your response. Please update the 'HEIGHT' field accordingly.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 22 Sep 2020 08:59:09 |
| Query 'Per CDM: Thanks for your response. Please update the 'HEIGHT' field accordingly.' answered by data change (Site from DM). | System | 15 Sep 2020 17:27:28 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Albert Garcia (b) (4) (b) (4) | 15 Sep 2020 17:27:28 |
| User opened query 'Per CDM: Thanks for your response. Please update the 'HEIGHT' field accordingly.' (Site from DM). | (b) (4), (b) (6) | 10 Sep 2020 13:35:37 |
| User closed query 'Per CDM: Per CCGs data is required please review and update accordingly ' (Site from DM). | (b) (4), (b) (6) | 10 Sep 2020 13:35:37 |
| Query 'Per CDM: Per CCGs data is required please review and update accordingly ' answered with 'ND' (Site from DM). | Albert Garcia (b) (4) (b) (4) | 04 Sep 2020 20:48:21 |
| User opened query 'Per CDM: Per CCGs data is required please review and update accordingly ' (Site from DM). | (b) (4), (b) (6) | 04 Sep 2020 17:35:21 |
| 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) | 04 Sep 2020 17:35:21 |
| 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). | Amber Vasquez (b) (4) (b) (4) | 01 Sep 2020 20:36:06 |
| User entered empty; reason for change Data Entry Error | Amber Vasquez (b) (4) (b) (4) | 01 Sep 2020 20:35:55 |
| 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 17:35:28 |
| User entered '172.7' cm | Amber Vasquez (b) (4) (b) (4) | 06 Aug 2020 19:29:34 |

US3222013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:03:07

Weight

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:10:27 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User closed query 'Per CDM: Thanks for your response. Please update the 'WEIGHT' field accordingly.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 22 Sep 2020 08:59:11 |
| Query 'Per CDM: Thanks for your response. Please update the 'WEIGHT' field accordingly.' answered by data change (Site from DM). | System | 15 Sep 2020 17:27:28 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Albert Garcia (b) (4) (b) (4) | 15 Sep 2020 17:27:28 |
| User opened query 'Per CDM: Thanks for your response. Please update the 'WEIGHT' field accordingly.' (Site from DM). | (b) (4), (b) (6) | 10 Sep 2020 13:35:49 |
| User closed query 'Per CDM: Per CCGs data is required please review and update accordingly ' (Site from DM). | (b) (4), (b) (6) | 10 Sep 2020 13:35:49 |
| Query 'Per CDM: Per CCGs data is required please review and update accordingly ' answered with 'ND' (Site from DM). | Albert Garcia (b) (4) (b) (4) | 04 Sep 2020 20:48:28 |
| User opened query 'Per CDM: Per CCGs data is required please review and update accordingly ' (Site from DM). | (b) (4), (b) (6) | 04 Sep 2020 17:35:25 |
| 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) | 04 Sep 2020 17:35:25 |
| 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). | Amber Vasquez (b) (4) (b) (4) | 01 Sep 2020 20:36:17 |
| User entered empty; reason for change Data Entry Error | Amber Vasquez (b) (4) (b) (4) | 01 Sep 2020 20:35:55 |
| 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 17:35:34 |
| User entered '84.4' kg | Amber Vasquez (b) (4) (b) (4) | 06 Aug 2020 19:29:34 |

US3222013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:03:07

Height

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:10:27 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User closed query 'Per CDM: Thanks for your response. Please update the 'HEIGHT' field accordingly.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 22 Sep 2020 08:59:09 |
| Query 'Per CDM: Thanks for your response. Please update the 'HEIGHT' field accordingly.' answered by data change (Site from DM). | System | 15 Sep 2020 17:27:28 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Albert Garcia (b) (4) (b) (4) | 15 Sep 2020 17:27:28 |
| User opened query 'Per CDM: Thanks for your response. Please update the 'HEIGHT' field accordingly.' (Site from DM). | (b) (4), (b) (6) | 10 Sep 2020 13:35:37 |
| User closed query 'Per CDM: Per CCGs data is required please review and update accordingly ' (Site from DM). | (b) (4), (b) (6) | 10 Sep 2020 13:35:37 |
| Query 'Per CDM: Per CCGs data is required please review and update accordingly ' answered with 'ND' (Site from DM). | Albert Garcia (b) (4) (b) (4) | 04 Sep 2020 20:48:21 |
| User opened query 'Per CDM: Per CCGs data is required please review and update accordingly ' (Site from DM). | (b) (4), (b) (6) | 04 Sep 2020 17:35:21 |
| 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) | 04 Sep 2020 17:35:21 |
| 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). | Amber Vasquez (b) (4) (b) (4) | 01 Sep 2020 20:36:06 |
| User entered empty; reason for change Data Entry Error | Amber Vasquez (b) (4) (b) (4) | 01 Sep 2020 20:35:55 |
| 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 17:35:28 |
| User entered '172.7' cm | Amber Vasquez (b) (4) (b) (4) | 06 Aug 2020 19:29:34 |

US3222013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:03:07

Weight

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:10:27 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User closed query 'Per CDM: Thanks for your response. Please update the 'WEIGHT' field accordingly.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 22 Sep 2020 08:59:11 |
| Query 'Per CDM: Thanks for your response. Please update the 'WEIGHT' field accordingly.' answered by data change (Site from DM). | System | 15 Sep 2020 17:27:28 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Albert Garcia (b) (4) (b) (4) | 15 Sep 2020 17:27:28 |
| User opened query 'Per CDM: Thanks for your response. Please update the 'WEIGHT' field accordingly.' (Site from DM). | (b) (4), (b) (6) | 10 Sep 2020 13:35:49 |
| User closed query 'Per CDM: Per CCGs data is required please review and update accordingly ' (Site from DM). | (b) (4), (b) (6) | 10 Sep 2020 13:35:49 |
| Query 'Per CDM: Per CCGs data is required please review and update accordingly ' answered with 'ND' (Site from DM). | Albert Garcia (b) (4) (b) (4) | 04 Sep 2020 20:48:28 |
| User opened query 'Per CDM: Per CCGs data is required please review and update accordingly ' (Site from DM). | (b) (4), (b) (6) | 04 Sep 2020 17:35:25 |
| 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) | 04 Sep 2020 17:35:25 |
| 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). | Amber Vasquez (b) (4) (b) (4) | 01 Sep 2020 20:36:17 |
| User entered empty; reason for change Data Entry Error | Amber Vasquez (b) (4) (b) (4) | 01 Sep 2020 20:35:55 |
| 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 17:35:34 |
| User entered '84.4' kg | Amber Vasquez (b) (4) (b) (4) | 06 Aug 2020 19:29:34 |

US3222013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:07

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:10:27 |
| User accepted default value 'Pre-Dose (PREDOSE)' | Amber Vasquez (b) (4) (b) (4) | 06 Aug 2020 19:29:34 |

US3222013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:07

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:10:27 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'Yes (Y)' | (b) (4) Amber Vasquez (b) (4) | 06 Aug 2020 19:29:34 |

US3222013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:07

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:10:27 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered '6 Aug 2020' | (b) (4) Amber Vasquez (b) (4) | 06 Aug 2020 19:29:34 |

US3222013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:10:27 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered '13:55' | (b) (4) Amber Vasquez (b) (4) | 06 Aug 2020 19:29:34 |

US3222013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:10:27 |
| User entered '6 Aug 2020 13:55' | System | 06 Aug 2020 19:29:34 |

US3222013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:07

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:10:27 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered '36.9' C | Amber Vasquez (b) (4) | 06 Aug 2020 19:29:34 |

US3222013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:07

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:10:27 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'Oral (Oral)' | (b) (4) Amber Vasquez (b) (4) | 06 Aug 2020 19:29:34 |

US3222013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:07

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:10:27 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered empty. | (b) (4) Amber Vasquez (b) (4) | 06 Aug 2020 19:29:34 |

US3222013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:07

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:10:27 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered '55' | (b) (4) Amber Vasquez (b) (4) | 06 Aug 2020 19:29:34 |

US3222013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:07

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:10:27 |
| User entered 'bpm' | System | 06 Aug 2020 19:29:34 |

US3222013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:10:27 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered '16' | Amber Vasquez (b) (4) | 06 Aug 2020 19:29:34 |

US3222013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:07

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:10:27 |
| User entered 'breaths/min' | System | 06 Aug 2020 19:29:34 |

US3222013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:07

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:10:27 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered '141' | (b) (4) Amber Vasquez (b) (4) | 06 Aug 2020 19:29:34 |

US3222013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:07

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:10:27 |
| User entered 'mmHg' | System | 06 Aug 2020 19:29:34 |

US3222013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:07

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:10:27 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered '85' | (b) (4) Amber Vasquez (b) (4) | 06 Aug 2020 19:29:34 |

US3222013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:07

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:10:27 |
| User entered 'mmHg' | System | 06 Aug 2020 19:29:34 |

US3222013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:03:07

Height

| Audit | User | Time (GMT) |
|---|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:10:27 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User closed query 'Per CDM: Thanks for your response. Please update the 'HEIGHT' field accordingly.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 22 Sep 2020 08:59:09 |
| Query 'Per CDM: Thanks for your response. Please update the 'HEIGHT' field accordingly.' answered by data change (Site from DM). | System | 15 Sep 2020 17:27:28 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Albert Garcia (b) (4) (b) (4) | 15 Sep 2020 17:27:28 |
| User opened query 'Per CDM: Thanks for your response. Please update the 'HEIGHT' field accordingly.' (Site from DM). | (b) (4), (b) (6) | 10 Sep 2020 13:35:37 |
| User closed query 'Per CDM: Per CCGs data is required please review and update accordingly ' (Site from DM). | (b) (4), (b) (6) | 10 Sep 2020 13:35:37 |
| Query 'Per CDM: Per CCGs data is required please review and update accordingly ' answered with 'ND' (Site from DM). | Albert Garcia (b) (4) (b) (4) | 04 Sep 2020 20:48:21 |
| User opened query 'Per CDM: Per CCGs data is required please review and update accordingly ' (Site from DM). | (b) (4), (b) (6) | 04 Sep 2020 17:35:21 |
| 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) | 04 Sep 2020 17:35:21 |
| 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). | Amber Vasquez (b) (4) (b) (4) | 01 Sep 2020 20:36:06 |
| User entered empty; reason for change Data Entry Error | Amber Vasquez (b) (4) (b) (4) | 01 Sep 2020 20:35:55 |
| 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 17:35:28 |
| User entered '172.7' cm | Amber Vasquez (b) (4) (b) (4) | 06 Aug 2020 19:29:34 |

US3222013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:03:07

Weight

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:10:27 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User closed query 'Per CDM: Thanks for your response. Please update the 'WEIGHT' field accordingly.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 22 Sep 2020 08:59:11 |
| Query 'Per CDM: Thanks for your response. Please update the 'WEIGHT' field accordingly.' answered by data change (Site from DM). | System | 15 Sep 2020 17:27:28 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Albert Garcia (b) (4) (b) (4) | 15 Sep 2020 17:27:28 |
| User opened query 'Per CDM: Thanks for your response. Please update the 'WEIGHT' field accordingly.' (Site from DM). | (b) (4), (b) (6) | 10 Sep 2020 13:35:49 |
| User closed query 'Per CDM: Per CCGs data is required please review and update accordingly ' (Site from DM). | (b) (4), (b) (6) | 10 Sep 2020 13:35:49 |
| Query 'Per CDM: Per CCGs data is required please review and update accordingly ' answered with 'ND' (Site from DM). | Albert Garcia (b) (4) (b) (4) | 04 Sep 2020 20:48:28 |
| User opened query 'Per CDM: Per CCGs data is required please review and update accordingly ' (Site from DM). | (b) (4), (b) (6) | 04 Sep 2020 17:35:25 |
| 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) | 04 Sep 2020 17:35:25 |
| 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). | Amber Vasquez (b) (4) (b) (4) | 01 Sep 2020 20:36:17 |
| User entered empty; reason for change Data Entry Error | Amber Vasquez (b) (4) (b) (4) | 01 Sep 2020 20:35:55 |
| 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 17:35:34 |
| User entered '84.4' kg | Amber Vasquez (b) (4) (b) (4) | 06 Aug 2020 19:29:34 |

US3222013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:07

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:10:27 |
| User accepted default value 'Post-Dose (POSTDOSE)' | Amber Vasquez (b) (4) (b) (4) | 06 Aug 2020 19:29:34 |

US3222013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:07

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:10:27 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'Yes (Y)' | (b) (4) Amber Vasquez (b) (4) | 06 Aug 2020 19:29:34 |

US3222013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:07

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:10:27 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered '6 Aug 2020' | (b) (4) Amber Vasquez (b) (4) | 06 Aug 2020 19:29:34 |

US3222013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|---|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:10:27 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' canceled (Site from System). | (b) (4) (b) (4), (b) (6) | 18 Aug 2020 17:16:49 |
| 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). | | 06 Aug 2020 19:29:34 |
| User entered '15:17' | Amber Vasquez (b) (4) (b) (4) | 06 Aug 2020 19:29:34 |

US3222013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:10:27 |
| User entered '6 Aug 2020 15:17' | System | 06 Aug 2020 19:29:34 |

US3222013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:07

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:10:27 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered '36.9' C | (b) (4) Amber Vasquez (b) (4) | 06 Aug 2020 19:29:34 |

US3222013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:07

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:10:27 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'Oral (Oral)' | (b) (4) Amber Vasquez (b) (4) | 06 Aug 2020 19:29:34 |

US3222013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:07

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:10:27 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered empty. | (b) (4) Amber Vasquez (b) (4) | 06 Aug 2020 19:29:34 |

US3222013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:07

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:10:27 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered '55' | (b) (4) Amber Vasquez (b) (4) | 06 Aug 2020 19:29:34 |

US3222013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:07

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:10:27 |
| User entered 'bpm' | System | 06 Aug 2020 19:29:34 |

US3222013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:10:27 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered '16' | (b) (4) Amber Vasquez (b) (4) | 06 Aug 2020 19:29:34 |

US3222013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:07

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:10:27 |
| User entered 'breaths/min' | System | 06 Aug 2020 19:29:34 |

US3222013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:07

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:10:27 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered '138' | (b) (4) Amber Vasquez (b) (4) | 06 Aug 2020 19:29:34 |

US3222013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:07

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:10:27 |
| User entered 'mmHg' | System | 06 Aug 2020 19:29:34 |

US3222013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:07

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:10:27 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered '85' | (b) (4) Amber Vasquez (b) (4) | 06 Aug 2020 19:29:34 |

US3222013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:07

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:10:27 |
| User entered 'mmHg' | System | 06 Aug 2020 19:29:34 |

US3222013

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:03:07

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:10:27 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'Yes (Y)' | (b) (4) Amber Vasquez (b) (4) | 06 Aug 2020 19:29:50 |

US3222013

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:03:07

Date of examination (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:10:27 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered '6 Aug 2020' | (b) (4) Amber Vasquez (b) (4) | 06 Aug 2020 19:29:50 |

US3222013

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:03:07

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:10:27 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'Yes (Y)' | Jennifer Dittman (b) (4) | 06 Aug 2020 18:45:15 |

US3222013

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:03:07

If No, reason not given

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:10:27 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered empty. | Jennifer Dittman (b) (4) | 06 Aug 2020 18:45:15 |

US3222013

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:03:07

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) | 03 Apr 2021 15:10:27 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered empty. | Jennifer Dittman (b) (4) | 06 Aug 2020 18:45:15 |

US3222013

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:03:07

[What was the study treatment?](#)

| Audit | User | Time (GMT) |
|-------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:10:27 |
| User entered 'MRNA-1273 OR PLACEBO' | System | 06 Aug 2020 18:45:15 |

US3222013

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:03:07

What was the treatment date? (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:10:27 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered '6 Aug 2020' | Jennifer Dittman (b) (4) | 06 Aug 2020 18:45:15 |

US3222013

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:03:07

[What was the treatment time? \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:10:27 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered '14:41' | Jennifer Dittman (b) (4) | 06 Aug 2020 18:45:15 |

US3222013

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:03:07

[Treatment Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:10:27 |
| User entered '6 Aug 2020 14:41' | System | 06 Aug 2020 18:45:15 |

US3222013

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:03:07

[Which arm was used to give treatment?](#)

| Audit | User | Time (GMT) |
|--------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:10:27 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'Right Arm (RIGHT ARM)' | Jennifer Dittman (b) (4) | 06 Aug 2020 18:45:15 |

US3222013

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:03:07

[What was the frequency of the study treatment dosing?](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:10:27 |
| User entered 'ONCE' | System | 06 Aug 2020 18:45:15 |

US3222013

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:03:07

What was the route of administration for the study treatment?

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:10:27 |
| User entered 'INTRAMUSCULAR' | System | 06 Aug 2020 18:45:15 |

US3222013

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:03:07

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:10:27 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'Yes (Y)' | (b) (4) Amber Vasquez (b) (4) | 06 Aug 2020 19:30:20 |

US3222013

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:03:07

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:10:27 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered '6 Aug 2020' | (b) (4) Amber Vasquez (b) (4) | 06 Aug 2020 19:30:20 |

US3222013

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:03:07

Collection time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:10:27 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered '14:03' | (b) (4) Amber Vasquez (b) (4) | 06 Aug 2020 19:30:20 |

US3222013

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:10:27 |
| User entered '6 Aug 2020 14:03' | System | 06 Aug 2020 19:30:20 |

US3222013

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:03:07

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:10:27 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered '6 Aug 2020' | (b) (4) Amber Vasquez (b) (4) | 06 Aug 2020 19:30:43 |

US3222013

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:03:07

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:10:27 |
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | Amber Vasquez (b) (4) (b) (4) | 06 Aug 2020 19:30:43 |

US3222013

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:03:07

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:10:27 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'Yes (Y)' | (b) (4) Amber Vasquez (b) (4) | 06 Aug 2020 19:30:43 |

US3222013

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:03:07

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:10:27 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered '14:03' reason for change: Data Entry Error | (b) (4) | |
| | Amber Vasquez (b) (4) | 06 Aug 2020 19:30:56 |
| User entered '14:06' | (b) (4) | |
| | Amber Vasquez (b) (4) | 06 Aug 2020 19:30:43 |
| | (b) (4) | |

US3222013

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:10:27 |
| User entered '6 Aug 2020 14:03' | System | 06 Aug 2020 19:30:56 |
| User entered '6 Aug 2020 14:06' | System | 06 Aug 2020 19:30:43 |

US3222013

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:03:07

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:10:27 |
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | Amber Vasquez (b) (4) | 06 Aug 2020 19:30:43 |

US3222013

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:03:07

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:10:27 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'No (N)' | (b) (4) Amber Vasquez (b) (4) | 06 Aug 2020 19:30:43 |

US3222013

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:03:07

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:10:27 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered empty. | (b) (4) Amber Vasquez (b) (4) | 06 Aug 2020 19:30:43 |

US3222013

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:10:27 |
| User entered empty. | System | 06 Aug 2020 19:30:43 |

US3222013

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:03:07

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:10:27 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'Yes (Y)' | (b) (4) Amber Vasquez (b) (4) | 06 Aug 2020 19:31:04 |

US3222013

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:03:07

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:10:27 |
| User entered '1' | System | 06 Aug 2020 19:31:04 |

US3222013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| Data entry locked. | System | 06 Aug 2020 18:45:15 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 06 Aug 2020 18:45:15 |

US3222013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-06T15:10:18', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '06fe4ce3-47a5-4c61-9a89-f1dfb114dbef' | System | 06 Aug 2020 19:10:39 |
| User entered 'Yes (Y)' | System | 06 Aug 2020 19:10:39 |

US3222013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-06T15:10:25', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '06fe4ce3-47a5-4c61-9a89-f1dfb114dbef' | System | 06 Aug 2020 19:10:39 |
| User entered '98.5' | System | 06 Aug 2020 19:10:39 |

US3222013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-06T15:10:30', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '06fe4ce3-47a5-4c61-9a89-f1dfb114dbef' | System | 06 Aug 2020 19:10:39 |
| User entered 'No (N)' | System | 06 Aug 2020 19:10:39 |

US3222013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-06T15:10:36', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '06fe4ce3-47a5-4c61-9a89-f1dfb114dbef' | System | 06 Aug 2020 19:10:39 |
| User entered '06 Aug 2020 15:10' | System | 06 Aug 2020 19:10:39 |

US3222013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| User entered '06 Aug 2020 15:01' | System | 06 Aug 2020 18:45:15 |

US3222013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| User entered '06 Aug 2020 17:31' | System | 06 Aug 2020 18:45:15 |

US3222013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| Data entry locked. | System | 06 Aug 2020 18:45:15 |
| User entered 'Day 1, after vaccination (at home)' | System | 06 Aug 2020 18:45:15 |

US3222013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| | | |

US3222013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| | | |

US3222013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| | | |

US3222013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| | | |

US3222013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

To **PREVENT** pain or fever from occurring

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| | | |

US3222013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| | | |

US3222013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| User entered '06 Aug 2020 18:26' | System | 06 Aug 2020 18:45:15 |

US3222013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| User entered '07 Aug 2020 11:59' | System | 06 Aug 2020 18:45:15 |

US3222013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| Data entry locked. | System | 06 Aug 2020 18:45:15 |
| User entered 'Day 2' | System | 06 Aug 2020 18:45:15 |

US3222013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:03:07

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-07T14:59:40', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'efa85946-a88c-4086-8dd8-f107d8056c75' | System | 07 Aug 2020 19:00:21 |
| User entered 'Yes (Y)' | System | 07 Aug 2020 19:00:21 |

US3222013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:03:07

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-07T14:59:56', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'efa85946-a88c-4086-8dd8-f107d8056c75' | System | 07 Aug 2020 19:00:21 |
| User entered '97.7' | System | 07 Aug 2020 19:00:21 |

US3222013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-07T15:00:01', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'efa85946-a88c-4086-8dd8-f107d8056c75' | System | 07 Aug 2020 19:00:21 |
| User entered 'No (N)' | System | 07 Aug 2020 19:00:21 |

US3222013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:03:07

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-07T15:00:17', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'efa85946-a88c-4086-8dd8-f107d8056c75' | System | 07 Aug 2020 19:00:21 |
| User entered '07 Aug 2020 15:00' | System | 07 Aug 2020 19:00:21 |

US3222013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:03:07

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| User entered '07 Aug 2020 12:00' | System | 06 Aug 2020 18:45:15 |

US3222013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:03:07

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| User entered '08 Aug 2020 11:59' | System | 06 Aug 2020 18:45:15 |

US3222013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| Data entry locked. | System | 06 Aug 2020 18:45:15 |
| User entered 'Day 3' | System | 06 Aug 2020 18:45:15 |

US3222013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:03:07

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-08T15:01:03', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '10770c22-41fb-4078-8bc9-d6c9f0a8fbcd' | System | 08 Aug 2020 19:02:15 |
| User entered 'Yes (Y)' | System | 08 Aug 2020 19:02:15 |

US3222013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:03:07

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-08T15:02:02', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '10770c22-41fb-4078-8bc9-d6c9f0a8fbcd' | System | 08 Aug 2020 19:02:15 |
| User entered '97.2' | System | 08 Aug 2020 19:02:15 |

US3222013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-08T15:02:05', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '10770c22-41fb-4078-8bc9-d6c9f0a8fbcd' | System | 08 Aug 2020 19:02:15 |
| User entered 'No (N)' | System | 08 Aug 2020 19:02:15 |

US3222013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:03:07

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-08T15:02:08', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '10770c22-41fb-4078-8bc9-d6c9f0a8fbcd' | System | 08 Aug 2020 19:02:15 |
| User entered '08 Aug 2020 15:02' | System | 08 Aug 2020 19:02:15 |

US3222013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:03:07

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| User entered '08 Aug 2020 12:00' | System | 06 Aug 2020 18:45:15 |

US3222013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:03:07

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| User entered '09 Aug 2020 11:59' | System | 06 Aug 2020 18:45:15 |

US3222013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| Data entry locked. | System | 06 Aug 2020 18:45:15 |
| User entered 'Day 4' | System | 06 Aug 2020 18:45:15 |

US3222013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:03:07

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-09T15:05:46', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'cc6c3294-6507-46b7-bfe9-dae6f863c4c3' | System | 09 Aug 2020 19:06:21 |
| User entered 'Yes (Y)' | System | 09 Aug 2020 19:06:21 |

US3222013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:03:07

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-09T15:05:55', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'cc6c3294-6507-46b7-bfe9-dae6f863c4c3' | System | 09 Aug 2020 19:06:21 |
| User entered '97.8' | System | 09 Aug 2020 19:06:21 |

US3222013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-09T15:06:00', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'cc6c3294-6507-46b7-bfe9-dae6f863c4c3' | System | 09 Aug 2020 19:06:21 |
| User entered 'No (N)' | System | 09 Aug 2020 19:06:21 |

US3222013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:03:07

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-09T15:06:15', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'cc6c3294-6507-46b7-bfe9-dae6f863c4c3' | System | 09 Aug 2020 19:06:21 |
| User entered '09 Aug 2020 15:06' | System | 09 Aug 2020 19:06:21 |

US3222013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:03:07

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| User entered '09 Aug 2020 12:00' | System | 06 Aug 2020 18:45:15 |

US3222013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:03:07

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| User entered '10 Aug 2020 11:59' | System | 06 Aug 2020 18:45:15 |

US3222013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| Data entry locked. | System | 06 Aug 2020 18:45:15 |
| User entered 'Day 5' | System | 06 Aug 2020 18:45:15 |

US3222013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:03:07

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-10T14:32:03', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '13875428-468b-42cc-aa2f-fb292a366312' | System | 10 Aug 2020 18:32:10 |
| User entered 'Yes (Y)' | System | 10 Aug 2020 18:32:10 |

US3222013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:03:07

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-10T14:31:51', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '13875428-468b-42cc-aa2f-fb292a366312' | System | 10 Aug 2020 18:32:10 |
| User entered '98.2' | System | 10 Aug 2020 18:32:10 |

US3222013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-10T14:31:58', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '13875428-468b-42cc-aa2f-fb292a366312' | System | 10 Aug 2020 18:32:10 |
| User entered 'No (N)' | System | 10 Aug 2020 18:32:10 |

US3222013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:03:07

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-10T14:32:08', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '13875428-468b-42cc-aa2f-fb292a366312' | System | 10 Aug 2020 18:32:10 |
| User entered '10 Aug 2020 14:32' | System | 10 Aug 2020 18:32:10 |

US3222013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:03:07

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| User entered '10 Aug 2020 12:00' | System | 06 Aug 2020 18:45:15 |

US3222013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:03:07

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| User entered '11 Aug 2020 11:59' | System | 06 Aug 2020 18:45:15 |

US3222013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| Data entry locked. | System | 06 Aug 2020 18:45:15 |
| User entered 'Day 6' | System | 06 Aug 2020 18:45:15 |

US3222013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:03:07

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-11T15:02:55', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '9095c7af-6042-469b-ae98-de751bbbe7b8' | System | 11 Aug 2020 19:03:09 |
| User entered 'Yes (Y)' | System | 11 Aug 2020 19:03:09 |

US3222013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:03:07

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-11T15:02:41', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '9095c7af-6042-469b-ae98-de751bbbe7b8' | System | 11 Aug 2020 19:03:09 |
| User entered '98.1' | System | 11 Aug 2020 19:03:09 |

US3222013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-11T15:02:45', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '9095c7af-6042-469b-ae98-de751bbbe7b8' | System | 11 Aug 2020 19:03:09 |
| User entered 'No (N)' | System | 11 Aug 2020 19:03:09 |

US3222013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:03:07

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-11T15:03:05', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '9095c7af-6042-469b-ae98-de751bbbe7b8' | System | 11 Aug 2020 19:03:09 |
| User entered '11 Aug 2020 15:03' | System | 11 Aug 2020 19:03:09 |

US3222013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:03:07

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| User entered '11 Aug 2020 12:00' | System | 06 Aug 2020 18:45:15 |

US3222013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:03:07

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| User entered '12 Aug 2020 11:59' | System | 06 Aug 2020 18:45:15 |

US3222013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| Data entry locked. | System | 06 Aug 2020 18:45:15 |
| User entered 'Day 7' | System | 06 Aug 2020 18:45:15 |

US3222013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:03:07

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-12T15:15:01', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '796dda72-050d-4d22-95a2-9e2d364ca548' | System | 12 Aug 2020 19:15:22 |
| User entered 'Yes (Y)' | System | 12 Aug 2020 19:15:22 |

US3222013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:03:07

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-12T15:15:09', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '796dda72-050d-4d22-95a2-9e2d364ca548' | System | 12 Aug 2020 19:15:22 |
| User entered '98.5' | System | 12 Aug 2020 19:15:22 |

US3222013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-12T15:15:13', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '796dda72-050d-4d22-95a2-9e2d364ca548' | System | 12 Aug 2020 19:15:22 |
| User entered 'No (N)' | System | 12 Aug 2020 19:15:22 |

US3222013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:03:07

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-12T15:15:19', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '796dda72-050d-4d22-95a2-9e2d364ca548' | System | 12 Aug 2020 19:15:22 |
| User entered '12 Aug 2020 15:15' | System | 12 Aug 2020 19:15:22 |

US3222013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:03:07

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| User entered '12 Aug 2020 12:00' | System | 06 Aug 2020 18:45:15 |

US3222013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:03:07

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| User entered '13 Aug 2020 11:59' | System | 06 Aug 2020 18:45:15 |

US3222013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| Data entry locked. | System | 06 Aug 2020 18:45:15 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 06 Aug 2020 18:45:15 |

US3222013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

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 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-06T15:10:46', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '2576cb13-3b7c-4d6b-9d85-45af62e80db8' | System | 06 Aug 2020 19:11:38 |
| User entered 'None (1)' | System | 06 Aug 2020 19:11:38 |

US3222013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-06T15:11:13', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '2576cb13-3b7c-4d6b-9d85-45af62e80db8' | System | 06 Aug 2020 19:11:38 |
| User entered 'No (N)' | System | 06 Aug 2020 19:11:38 |

US3222013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-06T15:11:17', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '2576cb13-3b7c-4d6b-9d85-45af62e80db8' | System | 06 Aug 2020 19:11:38 |
| User entered 'No (N)' | System | 06 Aug 2020 19:11:38 |

US3222013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

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 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-06T15:11:24', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '2576cb13-3b7c-4d6b-9d85-45af62e80db8' | System | 06 Aug 2020 19:11:38 |
| User entered 'None (1)' | System | 06 Aug 2020 19:11:38 |

US3222013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-06T15:11:35', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '2576cb13-3b7c-4d6b-9d85-45af62e80db8' | System | 06 Aug 2020 19:11:38 |
| User entered '06 Aug 2020 15:11' | System | 06 Aug 2020 19:11:38 |

US3222013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| User entered '06 Aug 2020 15:01' | System | 06 Aug 2020 18:45:15 |

US3222013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| User entered '06 Aug 2020 17:31' | System | 06 Aug 2020 18:45:15 |

US3222013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| Data entry locked. | System | 06 Aug 2020 18:45:15 |
| User entered 'Day 1, after vaccination (at home)' | System | 06 Aug 2020 18:45:15 |

US3222013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

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 00:40:33 |
| | | |

US3222013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| | | |

US3222013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

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 00:40:33 |
| | | |

US3222013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| | | |

US3222013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

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 00:40:33 |
| | | |

US3222013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

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 00:40:33 |
| | | |

US3222013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| | | |

US3222013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| User entered '06 Aug 2020 18:26' | System | 06 Aug 2020 18:45:15 |

US3222013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| User entered '07 Aug 2020 11:59' | System | 06 Aug 2020 18:45:15 |

US3222013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| Data entry locked. | System | 06 Aug 2020 18:45:15 |
| User entered 'Day 2' | System | 06 Aug 2020 18:45:15 |

US3222013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:03:07

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 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-07T15:00:45', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'b8c1e39e-518a-46d2-91cd-e00a1d383cd4' | System | 07 Aug 2020 19:03:58 |
| User entered 'Does not interfere with activity (2)' | System | 07 Aug 2020 19:03:58 |

US3222013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:03:07

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-07T15:00:54', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'b8c1e39e-518a-46d2-91cd-e00a1d383cd4' | System | 07 Aug 2020 19:03:58 |
| User entered 'No (N)' | System | 07 Aug 2020 19:03:58 |

US3222013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-07T15:01:00', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'b8c1e39e-518a-46d2-91cd-e00a1d383cd4' | System | 07 Aug 2020 19:03:58 |
| User entered 'Yes (Y)' | System | 07 Aug 2020 19:03:58 |

US3222013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:03:07

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 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-07T15:03:41', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'b8c1e39e-518a-46d2-91cd-e00a1d383cd4' | System | 07 Aug 2020 19:03:58 |
| User entered '3' | System | 07 Aug 2020 19:03:58 |

US3222013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:03:07

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 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-07T15:03:45', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'b8c1e39e-518a-46d2-91cd-e00a1d383cd4' | System | 07 Aug 2020 19:03:58 |
| User entered 'None (1)' | System | 07 Aug 2020 19:03:58 |

US3222013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:03:07

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-07T15:03:54', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'b8c1e39e-518a-46d2-91cd-e00a1d383cd4' | System | 07 Aug 2020 19:03:58 |
| User entered '07 Aug 2020 15:03' | System | 07 Aug 2020 19:03:58 |

US3222013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:03:07

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| User entered '07 Aug 2020 12:00' | System | 06 Aug 2020 18:45:15 |

US3222013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:03:07

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| User entered '08 Aug 2020 11:59' | System | 06 Aug 2020 18:45:15 |

US3222013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| Data entry locked. | System | 06 Aug 2020 18:45:15 |
| User entered 'Day 3' | System | 06 Aug 2020 18:45:15 |

US3222013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:03:07

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 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-08T15:02:19', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'f5f85c6b-eab5-4076-bfb2-a35f63ce3b6e' | System | 08 Aug 2020 19:02:52 |
| User entered 'None (1)' | System | 08 Aug 2020 19:02:52 |

US3222013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:03:07

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-08T15:02:23', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'f5f85c6b-eab5-4076-bfb2-a35f63ce3b6e' | System | 08 Aug 2020 19:02:52 |
| User entered 'No (N)' | System | 08 Aug 2020 19:02:52 |

US3222013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-08T15:02:39', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'f5f85c6b-eab5-4076-bfb2-a35f63ce3b6e' | System | 08 Aug 2020 19:02:52 |
| User entered 'No (N)' | System | 08 Aug 2020 19:02:52 |

US3222013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:03:07

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 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-08T15:02:42', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'f5f85c6b-eab5-4076-bfb2-a35f63ce3b6e' | System | 08 Aug 2020 19:02:52 |
| User entered 'None (1)' | System | 08 Aug 2020 19:02:52 |

US3222013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:03:07

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-08T15:02:47', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'f5f85c6b-eab5-4076-bfb2-a35f63ce3b6e' | System | 08 Aug 2020 19:02:52 |
| User entered '08 Aug 2020 15:02' | System | 08 Aug 2020 19:02:52 |

US3222013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:03:07

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| User entered '08 Aug 2020 12:00' | System | 06 Aug 2020 18:45:15 |

US3222013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:03:07

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| User entered '09 Aug 2020 11:59' | System | 06 Aug 2020 18:45:15 |

US3222013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| Data entry locked. | System | 06 Aug 2020 18:45:15 |
| User entered 'Day 4' | System | 06 Aug 2020 18:45:15 |

US3222013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:03:07

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 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-09T15:05:36', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'cd570e52-3a75-4ef7-a011-077c9d56beb7' | System | 09 Aug 2020 19:06:51 |
| User entered 'None (1)' | System | 09 Aug 2020 19:06:51 |

US3222013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:03:07

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-09T15:06:30', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'cd570e52-3a75-4ef7-a011-077c9d56beb7' | System | 09 Aug 2020 19:06:51 |
| User entered 'No (N)' | System | 09 Aug 2020 19:06:51 |

US3222013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-09T15:06:33', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'cd570e52-3a75-4ef7-a011-077c9d56beb7' | System | 09 Aug 2020 19:06:51 |
| User entered 'No (N)' | System | 09 Aug 2020 19:06:51 |

US3222013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:03:07

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 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-09T15:06:38', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'cd570e52-3a75-4ef7-a011-077c9d56beb7' | System | 09 Aug 2020 19:06:51 |
| User entered 'None (1)' | System | 09 Aug 2020 19:06:51 |

US3222013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:03:07

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-09T15:06:49', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'cd570e52-3a75-4ef7-a011-077c9d56beb7' | System | 09 Aug 2020 19:06:51 |
| User entered '09 Aug 2020 15:06' | System | 09 Aug 2020 19:06:51 |

US3222013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:03:07

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| User entered '09 Aug 2020 12:00' | System | 06 Aug 2020 18:45:15 |

US3222013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:03:07

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| User entered '10 Aug 2020 11:59' | System | 06 Aug 2020 18:45:15 |

US3222013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| Data entry locked. | System | 06 Aug 2020 18:45:15 |
| User entered 'Day 5' | System | 06 Aug 2020 18:45:15 |

US3222013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:03:07

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 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-10T14:32:15', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '8e8cfc57-78a2-4952-8ddc-6db24470aa4a' | System | 10 Aug 2020 18:32:37 |
| User entered 'None (1)' | System | 10 Aug 2020 18:32:37 |

US3222013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:03:07

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-10T14:32:20', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '8e8cfc57-78a2-4952-8ddc-6db24470aa4a' | System | 10 Aug 2020 18:32:37 |
| User entered 'No (N)' | System | 10 Aug 2020 18:32:37 |

US3222013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-10T14:32:23', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '8e8cfc57-78a2-4952-8ddc-6db24470aa4a' | System | 10 Aug 2020 18:32:37 |
| User entered 'No (N)' | System | 10 Aug 2020 18:32:37 |

US3222013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:03:07

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 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-10T14:32:26', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '8e8cfc57-78a2-4952-8ddc-6db24470aa4a' | System | 10 Aug 2020 18:32:37 |
| User entered 'None (1)' | System | 10 Aug 2020 18:32:37 |

US3222013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:03:07

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-10T14:32:32', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '8e8cfc57-78a2-4952-8ddc-6db24470aa4a' | System | 10 Aug 2020 18:32:37 |
| User entered '10 Aug 2020 14:32' | System | 10 Aug 2020 18:32:37 |

US3222013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:03:07

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| User entered '10 Aug 2020 12:00' | System | 06 Aug 2020 18:45:15 |

US3222013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:03:07

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| User entered '11 Aug 2020 11:59' | System | 06 Aug 2020 18:45:15 |

US3222013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| Data entry locked. | System | 06 Aug 2020 18:45:15 |
| User entered 'Day 6' | System | 06 Aug 2020 18:45:15 |

US3222013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:03:07

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 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-11T15:03:12', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '8801ce81-f384-4d25-ac6c-698e60edb3f1' | System | 11 Aug 2020 19:03:31 |
| User entered 'None (1)' | System | 11 Aug 2020 19:03:31 |

US3222013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:03:07

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-11T15:03:16', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '8801ce81-f384-4d25-ac6c-698e60edb3f1' | System | 11 Aug 2020 19:03:31 |
| User entered 'No (N)' | System | 11 Aug 2020 19:03:31 |

US3222013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-11T15:03:19', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '8801ce81-f384-4d25-ac6c-698e60edb3f1' | System | 11 Aug 2020 19:03:31 |
| User entered 'No (N)' | System | 11 Aug 2020 19:03:31 |

US3222013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:03:07

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 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-11T15:03:23', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '8801ce81-f384-4d25-ac6c-698e60edb3f1' | System | 11 Aug 2020 19:03:31 |
| User entered 'None (1)' | System | 11 Aug 2020 19:03:31 |

US3222013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:03:07

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-11T15:03:28', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '8801ce81-f384-4d25-ac6c-698e60edb3f1' | System | 11 Aug 2020 19:03:31 |
| User entered '11 Aug 2020 15:03' | System | 11 Aug 2020 19:03:31 |

US3222013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:03:07

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| User entered '11 Aug 2020 12:00' | System | 06 Aug 2020 18:45:15 |

US3222013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:03:07

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| User entered '12 Aug 2020 11:59' | System | 06 Aug 2020 18:45:15 |

US3222013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| Data entry locked. | System | 06 Aug 2020 18:45:15 |
| User entered 'Day 7' | System | 06 Aug 2020 18:45:15 |

US3222013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:03:07

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 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-12T15:15:27', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '5b774ce2-6e9e-46f9-b6c5-3ec83efb686e' | System | 12 Aug 2020 19:15:51 |
| User entered 'None (1)' | System | 12 Aug 2020 19:15:51 |

US3222013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:03:07

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-12T15:15:32', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '5b774ce2-6e9e-46f9-b6c5-3ec83efb686e' | System | 12 Aug 2020 19:15:51 |
| User entered 'No (N)' | System | 12 Aug 2020 19:15:51 |

US3222013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-12T15:15:36', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '5b774ce2-6e9e-46f9-b6c5-3ec83efb686e' | System | 12 Aug 2020 19:15:51 |
| User entered 'No (N)' | System | 12 Aug 2020 19:15:51 |

US3222013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:03:07

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 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-12T15:15:39', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '5b774ce2-6e9e-46f9-b6c5-3ec83efb686e' | System | 12 Aug 2020 19:15:51 |
| User entered 'None (1)' | System | 12 Aug 2020 19:15:51 |

US3222013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:03:07

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-12T15:15:45', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '5b774ce2-6e9e-46f9-b6c5-3ec83efb686e' | System | 12 Aug 2020 19:15:51 |
| User entered '12 Aug 2020 15:15' | System | 12 Aug 2020 19:15:51 |

US3222013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:03:07

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| User entered '12 Aug 2020 12:00' | System | 06 Aug 2020 18:45:15 |

US3222013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:03:07

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| User entered '13 Aug 2020 11:59' | System | 06 Aug 2020 18:45:15 |

US3222013

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| Data entry locked. | System | 06 Aug 2020 18:45:15 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 06 Aug 2020 18:45:15 |

US3222013

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-06T15:11:43', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '8ba3a8c2-091b-45ca-ac70-ea5a9fc67ce7' | System | 06 Aug 2020 19:12:15 |
| User entered 'None (0)' | System | 06 Aug 2020 19:12:15 |

US3222013

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-06T15:11:47', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '8ba3a8c2-091b-45ca-ac70-ea5a9fc67ce7' | System | 06 Aug 2020 19:12:15 |
| User entered 'None (0)' | System | 06 Aug 2020 19:12:15 |

US3222013

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-06T15:11:50', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '8ba3a8c2-091b-45ca-ac70-ea5a9fc67ce7' | System | 06 Aug 2020 19:12:15 |
| User entered 'None (0)' | System | 06 Aug 2020 19:12:15 |

US3222013

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-06T15:11:54', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '8ba3a8c2-091b-45ca-ac70-ea5a9fc67ce7' | System | 06 Aug 2020 19:12:15 |
| User entered 'None (0)' | System | 06 Aug 2020 19:12:15 |

US3222013

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-06T15:11:57', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '8ba3a8c2-091b-45ca-ac70-ea5a9fc67ce7' | System | 06 Aug 2020 19:12:15 |
| User entered 'None (0)' | System | 06 Aug 2020 19:12:15 |

US3222013

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-06T15:12:00', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '8ba3a8c2-091b-45ca-ac70-ea5a9fc67ce7' | System | 06 Aug 2020 19:12:15 |
| User entered 'None (0)' | System | 06 Aug 2020 19:12:15 |

US3222013

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

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 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-06T15:12:05', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '8ba3a8c2-091b-45ca-ac70-ea5a9fc67ce7' | System | 06 Aug 2020 19:12:15 |
| User entered 'No (N)' | System | 06 Aug 2020 19:12:15 |

US3222013

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-06T15:12:10', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '8ba3a8c2-091b-45ca-ac70-ea5a9fc67ce7' | System | 06 Aug 2020 19:12:15 |
| User entered '06 Aug 2020 15:12' | System | 06 Aug 2020 19:12:15 |

US3222013

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| User entered '06 Aug 2020 15:01' | System | 06 Aug 2020 18:45:15 |

US3222013

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| User entered '06 Aug 2020 17:31' | System | 06 Aug 2020 18:45:15 |

US3222013

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| Data entry locked. | System | 06 Aug 2020 18:45:15 |
| User entered 'Day 1, after vaccination (at home)' | System | 06 Aug 2020 18:45:15 |

US3222013

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

HEADACHE

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| | | |

US3222013

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

FATIGUE

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| | | |

US3222013

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| | | |

US3222013

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| | | |

US3222013

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| | | |

US3222013

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

CHILLS

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| | | |

US3222013

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

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 00:40:33 |
| | | |

US3222013

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| | | |

US3222013

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| User entered '06 Aug 2020 18:26' | System | 06 Aug 2020 18:45:15 |

US3222013

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| User entered '07 Aug 2020 11:59' | System | 06 Aug 2020 18:45:15 |

US3222013

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| Data entry locked. | System | 06 Aug 2020 18:45:15 |
| User entered 'Day 2' | System | 06 Aug 2020 18:45:15 |

US3222013

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:03:07

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-07T15:04:01', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '184ef74a-fca2-4b78-acf8-a40dc256e260' | System | 07 Aug 2020 19:04:32 |
| User entered 'None (0)' | System | 07 Aug 2020 19:04:32 |

US3222013

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:03:07

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-07T15:04:04', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '184ef74a-fca2-4b78-acf8-a40dc256e260' | System | 07 Aug 2020 19:04:32 |
| User entered 'None (0)' | System | 07 Aug 2020 19:04:32 |

US3222013

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:03:07

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-07T15:04:08', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '184ef74a-fca2-4b78-acf8-a40dc256e260' | System | 07 Aug 2020 19:04:32 |
| User entered 'None (0)' | System | 07 Aug 2020 19:04:32 |

US3222013

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:03:07

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-07T15:04:11', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '184ef74a-fca2-4b78-acf8-a40dc256e260' | System | 07 Aug 2020 19:04:32 |
| User entered 'None (0)' | System | 07 Aug 2020 19:04:32 |

US3222013

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:03:07

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-07T15:04:16', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '184ef74a-fca2-4b78-acf8-a40dc256e260' | System | 07 Aug 2020 19:04:32 |
| User entered 'None (0)' | System | 07 Aug 2020 19:04:32 |

US3222013

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:03:07

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-07T15:04:20', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '184ef74a-fca2-4b78-acf8-a40dc256e260' | System | 07 Aug 2020 19:04:32 |
| User entered 'None (0)' | System | 07 Aug 2020 19:04:32 |

US3222013

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:03:07

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 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-07T15:04:25', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '184ef74a-fca2-4b78-acf8-a40dc256e260' | System | 07 Aug 2020 19:04:32 |
| User entered 'No (N)' | System | 07 Aug 2020 19:04:32 |

US3222013

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:03:07

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-07T15:04:30', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '184ef74a-fca2-4b78-acf8-a40dc256e260' | System | 07 Aug 2020 19:04:32 |
| User entered '07 Aug 2020 15:04' | System | 07 Aug 2020 19:04:32 |

US3222013

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:03:07

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| User entered '07 Aug 2020 12:00' | System | 06 Aug 2020 18:45:15 |

US3222013

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:03:07

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| User entered '08 Aug 2020 11:59' | System | 06 Aug 2020 18:45:15 |

US3222013

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| Data entry locked. | System | 06 Aug 2020 18:45:15 |
| User entered 'Day 3' | System | 06 Aug 2020 18:45:15 |

US3222013

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:03:07

HEADACHE

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-08T15:02:53', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '3f6e289c-eebc-4ce7-9d17-13ef8054eae' | System | 08 Aug 2020 19:03:23 |
| User entered 'None (0)' | System | 08 Aug 2020 19:03:23 |

US3222013

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:03:07

FATIGUE

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-08T15:02:56', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '3f6e289c-eebc-4ce7-9d17-13ef8054eae' | System | 08 Aug 2020 19:03:23 |
| User entered 'None (0)' | System | 08 Aug 2020 19:03:23 |

US3222013

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:03:07

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-08T15:03:02', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '3f6e289c-eebc-4ce7-9d17-13ef8054eae' | System | 08 Aug 2020 19:03:23 |
| User entered 'None (0)' | System | 08 Aug 2020 19:03:23 |

US3222013

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:03:07

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-08T15:03:06', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '3f6e289c-eebc-4ce7-9d17-13ef8054eae' | System | 08 Aug 2020 19:03:23 |
| User entered 'None (0)' | System | 08 Aug 2020 19:03:23 |

US3222013

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:03:07

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-08T15:03:09', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '3f6e289c-eebc-4ce7-9d17-13ef8054eae' | System | 08 Aug 2020 19:03:23 |
| User entered 'None (0)' | System | 08 Aug 2020 19:03:23 |

US3222013

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:03:07

CHILLS

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-08T15:03:11', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '3f6e289c-eebc-4ce7-9d17-13ef8054eae' | System | 08 Aug 2020 19:03:23 |
| User entered 'None (0)' | System | 08 Aug 2020 19:03:23 |

US3222013

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:03:07

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 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-08T15:03:16', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '3f6e289c-eebc-4ce7-9d17-13ef8054eae' | System | 08 Aug 2020 19:03:23 |
| User entered 'No (N)' | System | 08 Aug 2020 19:03:23 |

US3222013

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:03:07

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-08T15:03:20', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '3f6e289c-eebc-4ce7-9d17-13ef8054eae' | System | 08 Aug 2020 19:03:23 |
| User entered '08 Aug 2020 15:03' | System | 08 Aug 2020 19:03:23 |

US3222013

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:03:07

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| User entered '08 Aug 2020 12:00' | System | 06 Aug 2020 18:45:15 |

US3222013

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:03:07

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| User entered '09 Aug 2020 11:59' | System | 06 Aug 2020 18:45:15 |

US3222013

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| Data entry locked. | System | 06 Aug 2020 18:45:15 |
| User entered 'Day 4' | System | 06 Aug 2020 18:45:15 |

US3222013

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:03:07

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-09T15:06:56', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '3e7fec8a-f1c1-40e6-b228-e4552d312bec' | System | 09 Aug 2020 19:07:29 |
| User entered 'None (0)' | System | 09 Aug 2020 19:07:29 |

US3222013

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:03:07

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-09T15:06:59', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '3e7fec8a-f1c1-40e6-b228-e4552d312bec' | System | 09 Aug 2020 19:07:29 |
| User entered 'None (0)' | System | 09 Aug 2020 19:07:29 |

US3222013

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:03:07

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-09T15:07:02', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '3e7fec8a-f1c1-40e6-b228-e4552d312bec' | System | 09 Aug 2020 19:07:29 |
| User entered 'None (0)' | System | 09 Aug 2020 19:07:29 |

US3222013

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:03:07

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-09T15:07:05', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '3e7fec8a-f1c1-40e6-b228-e4552d312bec' | System | 09 Aug 2020 19:07:29 |
| User entered 'None (0)' | System | 09 Aug 2020 19:07:29 |

US3222013

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:03:07

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-09T15:07:09', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '3e7fec8a-f1c1-40e6-b228-e4552d312bec' | System | 09 Aug 2020 19:07:29 |
| User entered 'None (0)' | System | 09 Aug 2020 19:07:29 |

US3222013

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:03:07

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-09T15:07:12', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '3e7fec8a-f1c1-40e6-b228-e4552d312bec' | System | 09 Aug 2020 19:07:29 |
| User entered 'None (0)' | System | 09 Aug 2020 19:07:29 |

US3222013

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:03:07

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 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-09T15:07:16', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '3e7fec8a-f1c1-40e6-b228-e4552d312bec' | System | 09 Aug 2020 19:07:29 |
| User entered 'No (N)' | System | 09 Aug 2020 19:07:29 |

US3222013

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:03:07

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-09T15:07:26', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '3e7fec8a-f1c1-40e6-b228-e4552d312bec' | System | 09 Aug 2020 19:07:29 |
| User entered '09 Aug 2020 15:07' | System | 09 Aug 2020 19:07:29 |

US3222013

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:03:07

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| User entered '09 Aug 2020 12:00' | System | 06 Aug 2020 18:45:15 |

US3222013

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:03:07

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| User entered '10 Aug 2020 11:59' | System | 06 Aug 2020 18:45:15 |

US3222013

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| Data entry locked. | System | 06 Aug 2020 18:45:15 |
| User entered 'Day 5' | System | 06 Aug 2020 18:45:15 |

US3222013

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:03:07

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-10T14:32:39', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '71e2e3c8-c5a3-4155-9f18-5a604703ac91' | System | 10 Aug 2020 18:33:20 |
| User entered 'None (0)' | System | 10 Aug 2020 18:33:20 |

US3222013

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:03:07

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-10T14:32:43', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '71e2e3c8-c5a3-4155-9f18-5a604703ac91' | System | 10 Aug 2020 18:33:20 |
| User entered 'None (0)' | System | 10 Aug 2020 18:33:20 |

US3222013

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:03:07

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-10T14:32:46', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '71e2e3c8-c5a3-4155-9f18-5a604703ac91' | System | 10 Aug 2020 18:33:20 |
| User entered 'None (0)' | System | 10 Aug 2020 18:33:20 |

US3222013

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:03:07

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-10T14:32:50', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '71e2e3c8-c5a3-4155-9f18-5a604703ac91' | System | 10 Aug 2020 18:33:20 |
| User entered 'None (0)' | System | 10 Aug 2020 18:33:20 |

US3222013

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:03:07

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-10T14:32:53', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '71e2e3c8-c5a3-4155-9f18-5a604703ac91' | System | 10 Aug 2020 18:33:20 |
| User entered 'None (0)' | System | 10 Aug 2020 18:33:20 |

US3222013

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:03:07

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-10T14:32:56', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '71e2e3c8-c5a3-4155-9f18-5a604703ac91' | System | 10 Aug 2020 18:33:20 |
| User entered 'None (0)' | System | 10 Aug 2020 18:33:20 |

US3222013

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:03:07

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 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-10T14:33:03', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '71e2e3c8-c5a3-4155-9f18-5a604703ac91' | System | 10 Aug 2020 18:33:20 |
| User entered 'No (N)' | System | 10 Aug 2020 18:33:20 |

US3222013

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:03:07

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-10T14:33:16', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '71e2e3c8-c5a3-4155-9f18-5a604703ac91' | System | 10 Aug 2020 18:33:20 |
| User entered '10 Aug 2020 14:33' | System | 10 Aug 2020 18:33:20 |

US3222013

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:03:07

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| User entered '10 Aug 2020 12:00' | System | 06 Aug 2020 18:45:15 |

US3222013

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:03:07

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| User entered '11 Aug 2020 11:59' | System | 06 Aug 2020 18:45:15 |

US3222013

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| Data entry locked. | System | 06 Aug 2020 18:45:15 |
| User entered 'Day 6' | System | 06 Aug 2020 18:45:15 |

US3222013

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:03:07

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-11T15:03:35', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '7b782af5-a882-4b51-beae-238b0ca18f75' | System | 11 Aug 2020 19:04:15 |
| User entered 'None (0)' | System | 11 Aug 2020 19:04:15 |

US3222013

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:03:07

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-11T15:03:38', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '7b782af5-a882-4b51-beae-238b0ca18f75' | System | 11 Aug 2020 19:04:15 |
| User entered 'None (0)' | System | 11 Aug 2020 19:04:15 |

US3222013

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:03:07

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-11T15:03:42', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '7b782af5-a882-4b51-beae-238b0ca18f75' | System | 11 Aug 2020 19:04:15 |
| User entered 'None (0)' | System | 11 Aug 2020 19:04:15 |

US3222013

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:03:07

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-11T15:03:45', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '7b782af5-a882-4b51-beae-238b0ca18f75' | System | 11 Aug 2020 19:04:15 |
| User entered 'None (0)' | System | 11 Aug 2020 19:04:15 |

US3222013

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:03:07

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-11T15:03:48', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '7b782af5-a882-4b51-beae-238b0ca18f75' | System | 11 Aug 2020 19:04:15 |
| User entered 'None (0)' | System | 11 Aug 2020 19:04:15 |

US3222013

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:03:07

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-11T15:03:52', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '7b782af5-a882-4b51-beae-238b0ca18f75' | System | 11 Aug 2020 19:04:15 |
| User entered 'None (0)' | System | 11 Aug 2020 19:04:15 |

US3222013

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:03:07

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 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-11T15:03:58', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '7b782af5-a882-4b51-beae-238b0ca18f75' | System | 11 Aug 2020 19:04:15 |
| User entered 'No (N)' | System | 11 Aug 2020 19:04:15 |

US3222013

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:03:07

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-11T15:04:13', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '7b782af5-a882-4b51-beae-238b0ca18f75' | System | 11 Aug 2020 19:04:15 |
| User entered '11 Aug 2020 15:04' | System | 11 Aug 2020 19:04:15 |

US3222013

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:03:07

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| User entered '11 Aug 2020 12:00' | System | 06 Aug 2020 18:45:15 |

US3222013

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:03:07

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| User entered '12 Aug 2020 11:59' | System | 06 Aug 2020 18:45:15 |

US3222013

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| Data entry locked. | System | 06 Aug 2020 18:45:15 |
| User entered 'Day 7' | System | 06 Aug 2020 18:45:15 |

US3222013

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:03:07

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-12T15:15:53', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'f0d9bd62-cf7b-4c7c-91ff-368fa2f32cab' | System | 12 Aug 2020 19:16:38 |
| User entered 'None (0)' | System | 12 Aug 2020 19:16:38 |

US3222013

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:03:07

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-12T15:15:56', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'f0d9bd62-cf7b-4c7c-91ff-368fa2f32cab' | System | 12 Aug 2020 19:16:38 |
| User entered 'None (0)' | System | 12 Aug 2020 19:16:38 |

US3222013

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:03:07

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-12T15:16:00', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'f0d9bd62-cf7b-4c7c-91ff-368fa2f32cab' | System | 12 Aug 2020 19:16:38 |
| User entered 'None (0)' | System | 12 Aug 2020 19:16:38 |

US3222013

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:03:07

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-12T15:16:03', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'f0d9bd62-cf7b-4c7c-91ff-368fa2f32cab' | System | 12 Aug 2020 19:16:38 |
| User entered 'None (0)' | System | 12 Aug 2020 19:16:38 |

US3222013

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:03:07

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-12T15:16:06', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'f0d9bd62-cf7b-4c7c-91ff-368fa2f32cab' | System | 12 Aug 2020 19:16:38 |
| User entered 'None (0)' | System | 12 Aug 2020 19:16:38 |

US3222013

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:03:07

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-12T15:16:10', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'f0d9bd62-cf7b-4c7c-91ff-368fa2f32cab' | System | 12 Aug 2020 19:16:38 |
| User entered 'None (0)' | System | 12 Aug 2020 19:16:38 |

US3222013

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:03:07

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 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-12T15:16:18', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'f0d9bd62-cf7b-4c7c-91ff-368fa2f32cab' | System | 12 Aug 2020 19:16:38 |
| User entered 'No (N)' | System | 12 Aug 2020 19:16:38 |

US3222013

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:03:07

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-08-12T15:16:36', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'f0d9bd62-cf7b-4c7c-91ff-368fa2f32cab' | System | 12 Aug 2020 19:16:38 |
| User entered '12 Aug 2020 15:16' | System | 12 Aug 2020 19:16:38 |

US3222013

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:03:07

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| User entered '12 Aug 2020 12:00' | System | 06 Aug 2020 18:45:15 |

US3222013

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:03:07

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| User entered '13 Aug 2020 11:59' | System | 06 Aug 2020 18:45:15 |

US3222013

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:07

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:10:27 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'Yes (Y)' | (b) (4) Amber Vasquez (b) (4) | 13 Aug 2020 17:29:51 |

US3222013

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:10:27 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered '13 Aug 2020' | (b) (4) Amber Vasquez (b) (4) | 13 Aug 2020 17:29:51 |

US3222013

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:07

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:10:27 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) Amber Vasquez (b) (4) | 13 Aug 2020 17:29:51 |

US3222013

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:07

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:10:27 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered empty. | Amber Vasquez (b) (4) | 13 Aug 2020 17:29:51 |

US3222013

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:07

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:10:27 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'Yes (Y)' | (b) (4) Amber Vasquez (b) (4) | 13 Aug 2020 17:29:55 |

US3222013

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:07

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:10:27 |
| User entered '1' | System | 13 Aug 2020 17:29:55 |

US3222013

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:07

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:26:28 |
| Data hard unlocked. | (b) (4), (b) (6) | 22 Apr 2021 19:09:57 |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:10:27 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'Yes (Y)' | Crystal Paccione (b) (4) | 04 Sep 2020 19:51:41 |

US3222013

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:07

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:26:28 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 13:33:59 |
| Signature has been broken. | douglas winter (b) (4) | 23 Apr 2021 13:03:28 |
| User entered '20 Aug 2020' reason for change: Data Entry Error | douglas winter (b) (4) | 23 Apr 2021 13:03:28 |
| Data hard unlocked. | (b) (4), (b) (6) | 22 Apr 2021 19:09:57 |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:10:27 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User closed query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System). | (b) (4), (b) (6) | 13 Sep 2020 15:30:25 |
| Query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'DATA ENTERED IS CORRECT' (Site from System). | Albert Garcia (b) (4) | 04 Sep 2020 20:45:52 |
| User opened query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System). | System | 04 Sep 2020 19:51:41 |
| User entered '4 Sep 2020' | Crystal Paccione (b) (4) | 04 Sep 2020 19:51:41 |

US3222013

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:07

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:26:28 |
| Data hard unlocked. | (b) (4), (b) (6) | 22 Apr 2021 19:09:57 |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:10:27 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'Contact Made (CONTACT MADE)' | Crystal Paccione (b) (4) | 04 Sep 2020 19:51:41 |

US3222013

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:07

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:26:28 |
| Data hard unlocked. | (b) (4), (b) (6) | 22 Apr 2021 19:09:57 |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:10:27 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered empty. | Crystal Paccione (b) (4) | 04 Sep 2020 19:51:41 |

US3222013

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:07

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:26:28 |
| Data hard unlocked. | (b) (4), (b) (6) | 22 Apr 2021 19:10:04 |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:10:27 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'Yes (Y)' | Crystal Paccione (b) (4) | 04 Sep 2020 19:51:48 |

US3222013

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:07

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:26:28 |
| Data hard unlocked. | (b) (4), (b) (6) | 22 Apr 2021 19:10:04 |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:10:27 |
| User entered 'l' | System | 04 Sep 2020 19:51:48 |

US3222013

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:07

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:28:53 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 17:28:49 |
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 05:07:10 |
| Data hard unlocked. | (b) (4), (b) (6) | 22 Apr 2021 19:10:18 |
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 19:10:14 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'Yes (Y)' | Crystal Paccione (b) (4) | 04 Sep 2020 19:52:10 |

US3222013

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:07

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:28:53 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 17:28:49 |
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 05:07:10 |
| User signature succeeded. | Bruce Rankin (b) (4) | 26 Apr 2021 13:33:59 |
| Data hard unlocked. | (b) (4), (b) (6) | 22 Apr 2021 19:10:18 |
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 19:10:14 |
| User closed query 'Visits Safety Call Day 15 and Safety Call Day 22 are both dated 04SEP2020, however it is not possible for these two visits to be on the same day per the schedule of events. Please confirm the date for each visit or amend one of them to 'No' if it was not completed.' (Site from DM). | (b) (4), (b) (6) | 15 Apr 2021 09:19:57 |
| Query 'Visits Safety Call Day 15 and Safety Call Day 22 are both dated 04SEP2020, however it is not possible for these two visits to be on the same day per the schedule of events. Please confirm the date for each visit or amend one of them to 'No' if it was not completed.' answered with 'This has been updated. Safety call Day 15 needs to be updated but it's locked and I am unable to change it.' (Site from DM). | Jennifer Dittman (b) (4) | 08 Apr 2021 18:36:46 |
| Signature has been broken. | (b) (4) | |
| User entered '27 Aug 2020' reason for change: Data Entry Error | Jennifer Dittman (b) (4) | 08 Apr 2021 18:35:55 |
| User opened query 'Visits Safety Call Day 15 and Safety Call Day 22 are both dated 04SEP2020, however it is not possible for these two visits to be on the same day per the schedule of events. Please confirm the date for each visit or amend one of them to 'No' if it was not completed.' (Site from DM). | (b) (4), (b) (6) | 26 Mar 2021 11:02:16 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User closed query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System). | (b) (4), (b) (6) | 13 Sep 2020 15:30:05 |

US3222013

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:07

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'DATA ENTERED IS CORRECT' (Site from System). | Albert Garcia (b) (4) | 04 Sep 2020 20:47:58 |
| User opened query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System). | System | 04 Sep 2020 19:52:10 |
| User entered '4 Sep 2020' | Crystal Paccione (b) (4) | 04 Sep 2020 19:52:10 |

US3222013

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:07

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:28:53 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 17:28:49 |
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 05:07:10 |
| Data hard unlocked. | (b) (4), (b) (6) | 22 Apr 2021 19:10:18 |
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 19:10:14 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'Contact Made (CONTACT MADE)' | Crystal Paccione (b) (4) | 04 Sep 2020 19:52:10 |

US3222013

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:07

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:28:53 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 17:28:49 |
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 05:07:10 |
| Data hard unlocked. | (b) (4), (b) (6) | 22 Apr 2021 19:10:18 |
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 19:10:14 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered empty. | Crystal Paccione (b) (4) | 04 Sep 2020 19:52:10 |

US3222013

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:07

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:28:53 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 17:28:57 |
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 05:07:10 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'Yes (Y)' | Crystal Paccione (b) (4) | 04 Sep 2020 19:52:17 |

US3222013

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:07

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:28:53 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 17:28:57 |
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 05:07:10 |
| User entered 'l' | System | 04 Sep 2020 19:52:17 |

US3222013

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:03:07

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'Yes (Y)' | (b) (4) Crystal Paccione (b) (4) | 04 Sep 2020 19:54:49 |

US3222013

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:03:07

Visit date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User closed query 'Per CDM: Safety Call Day 15 and Visit 2 Day 29 were performed on same day (4SEP2020). Kindly review and update accordingly. Else clarify. ' (Site from DM). | (b) (4), (b) (6) | 26 Apr 2021 08:27:42 |
| Query 'Per CDM: Safety Call Day 15 and Visit 2 Day douglas winter 29 were performed on same day (4SEP2020). Kindly review and update accordingly. Else clarify. ' answered with 'CORRECTED SC D15 DATE TO 20AUG2020' (Site from DM). | (b) (4) (b) (4) | 23 Apr 2021 13:04:25 |
| User opened query 'Per CDM: Safety Call Day 15 and Visit 2 Day 29 were performed on same day (4SEP2020). Kindly review and update accordingly. Else clarify. ' (Site from DM). | (b) (4), (b) (6) | 10 Apr 2021 13:52:46 |
| User signature succeeded. | Bruce Rankin (b) (4) (b) (4) | 16 Feb 2021 16:27:05 |
| User entered '4 Sep 2020' | Crystal Paccione (b) (4) (b) (4) | 04 Sep 2020 19:54:49 |

US3222013

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|--------------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'Clinic (Clinic)' | (b) (4) Crystal Paccione (b) (4) (b) (4) | 04 Sep 2020 19:54:49 |

US3222013

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:03:07

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User entered 'VISIT2' | System | 04 Sep 2020 19:54:49 |

US3222013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:07

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User accepted default value 'Pre-Dose (PREDOSE)' | Amber Vasquez (b) (4) (b) (4) | 05 Sep 2020 12:53:11 |

US3222013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:07

Were vital signs assessed?

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'Yes (Y)' | (b) (4) Amber Vasquez (b) (4) | 05 Sep 2020 12:53:11 |

US3222013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:07

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered '4 Sep 2020' | (b) (4) Amber Vasquez (b) (4) | 05 Sep 2020 12:53:11 |

US3222013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered '15:04' | (b) (4) Amber Vasquez (b) (4) | 05 Sep 2020 12:53:11 |

US3222013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User entered '4 Sep 2020 15:04' | System | 05 Sep 2020 12:53:11 |

US3222013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:07

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered '36.8' C | (b) (4) Amber Vasquez (b) (4) | 05 Sep 2020 12:53:11 |

US3222013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:07

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'Oral (Oral)' | (b) (4) Amber Vasquez (b) (4) | 05 Sep 2020 12:53:11 |

US3222013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:07

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered empty. | (b) (4) Amber Vasquez (b) (4) | 05 Sep 2020 12:53:11 |

US3222013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:07

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered '57' | (b) (4) Amber Vasquez (b) (4) | 05 Sep 2020 12:53:11 |

US3222013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:07

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User entered 'bpm' | System | 05 Sep 2020 12:53:11 |

US3222013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered '16' | (b) (4) Amber Vasquez (b) (4) | 05 Sep 2020 12:53:11 |

US3222013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:07

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User entered 'breaths/min' | System | 05 Sep 2020 12:53:11 |

US3222013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:07

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered '150' | (b) (4) Amber Vasquez (b) (4) | 05 Sep 2020 12:53:11 |

US3222013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:07

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User entered 'mmHg' | System | 05 Sep 2020 12:53:11 |

US3222013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:07

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered '87' | (b) (4) Amber Vasquez (b) (4) | 05 Sep 2020 12:53:11 |

US3222013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:03:07

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User entered 'mmHg' | System | 05 Sep 2020 12:53:11 |

US3222013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:07

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User accepted default value 'Post-Dose (POSTDOSE)' | Amber Vasquez (b) (4) (b) (4) | 05 Sep 2020 12:53:11 |

US3222013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:07

Were vital signs assessed?

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'Yes (Y)' | (b) (4) Amber Vasquez (b) (4) | 05 Sep 2020 12:53:11 |

US3222013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:07

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered '4 Sep 2020' | (b) (4) Amber Vasquez (b) (4) | 05 Sep 2020 12:53:11 |

US3222013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered '16:12' | (b) (4) Amber Vasquez (b) (4) | 05 Sep 2020 12:53:11 |

US3222013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User entered '4 Sep 2020 16:12' | System | 05 Sep 2020 12:53:11 |

US3222013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:07

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered '36.7' C | (b) (4) Amber Vasquez (b) (4) | 05 Sep 2020 12:53:11 |

US3222013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:07

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'Oral (Oral)' | (b) (4) Amber Vasquez (b) (4) | 05 Sep 2020 12:53:11 |

US3222013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:07

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered empty. | (b) (4) Amber Vasquez (b) (4) | 05 Sep 2020 12:53:11 |

US3222013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:07

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered '60' | (b) (4) Amber Vasquez (b) (4) | 05 Sep 2020 12:53:11 |

US3222013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:07

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User entered 'bpm' | System | 05 Sep 2020 12:53:11 |

US3222013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered '18' | (b) (4) Amber Vasquez (b) (4) | 05 Sep 2020 12:53:11 |

US3222013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:07

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User entered 'breaths/min' | System | 05 Sep 2020 12:53:11 |

US3222013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:07

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered '140' | (b) (4) Amber Vasquez (b) (4) | 05 Sep 2020 12:53:11 |

US3222013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:07

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User entered 'mmHg' | System | 05 Sep 2020 12:53:11 |

US3222013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:07

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered '70' | (b) (4) Amber Vasquez (b) (4) | 05 Sep 2020 12:53:11 |

US3222013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:03:07

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User entered 'mmHg' | System | 05 Sep 2020 12:53:11 |

US3222013

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:03:07

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'Yes (Y)' | (b) (4) Amber Vasquez (b) (4) | 05 Sep 2020 12:53:21 |

US3222013

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:03:07

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered '4 Sep 2020' | (b) (4) Amber Vasquez (b) (4) | 05 Sep 2020 12:53:21 |

US3222013

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:03:07

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'Yes (Y)' | (b) (4) Crystal Paccione (b) (4) | 04 Sep 2020 19:55:59 |

US3222013

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:03:07

If No, reason not given

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered empty. | (b) (4) Crystal Paccione (b) (4) | 04 Sep 2020 19:55:59 |

US3222013

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered empty. | Crystal Paccione (b) (4) | 04 Sep 2020 19:55:59 |

US3222013

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:03:07

[What was the study treatment?](#)

| Audit | User | Time (GMT) |
|-------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User entered 'MRNA-1273 OR PLACEBO' | System | 04 Sep 2020 19:55:59 |

US3222013

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:03:07

What was the treatment date? (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered '4 Sep 2020' | (b) (4) Crystal Paccione (b) (4) | 04 Sep 2020 19:55:59 |

US3222013

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:03:07

[What was the treatment time? \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered '15:37' | (b) (4) Crystal Paccione (b) (4) | 04 Sep 2020 19:55:59 |

US3222013

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:03:07

[Treatment Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User entered '4 Sep 2020 15:37' | System | 04 Sep 2020 19:55:59 |

US3222013

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:03:07

[Which arm was used to give treatment?](#)

| Audit | User | Time (GMT) |
|--------------------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'Right Arm (RIGHT ARM)' | (b) (4) Crystal Paccione (b) (4) | 04 Sep 2020 19:55:59 |

US3222013

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:03:07

[What was the frequency of the study treatment dosing?](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User entered 'ONCE' | System | 04 Sep 2020 19:55:59 |

US3222013

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:03:07

What was the route of administration for the study treatment?

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User entered 'INTRAMUSCULAR' | System | 04 Sep 2020 19:55:59 |

US3222013

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:03:07

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'Yes (Y)' | (b) (4) Amber Vasquez (b) (4) | 05 Sep 2020 12:53:41 |

US3222013

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:03:07

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered '4 Sep 2020' | (b) (4) Amber Vasquez (b) (4) | 05 Sep 2020 12:53:41 |

US3222013

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:03:07

Collection time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered '15:20' | (b) (4) Amber Vasquez (b) (4) | 05 Sep 2020 12:53:41 |

US3222013

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User entered '4 Sep 2020 15:20' | System | 05 Sep 2020 12:53:41 |

US3222013

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:03:07

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered '4 Sep 2020' | (b) (4) Amber Vasquez (b) (4) | 05 Sep 2020 12:53:58 |

US3222013

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:03:07

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | Amber Vasquez (b) (4) (b) (4) | 05 Sep 2020 12:53:58 |

US3222013

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:03:07

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'Yes (Y)' | (b) (4) Amber Vasquez (b) (4) | 05 Sep 2020 12:53:58 |

US3222013

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:03:07

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered '15:28' | (b) (4) Amber Vasquez (b) (4) | 05 Sep 2020 12:53:58 |

US3222013

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User entered '4 Sep 2020 15:28' | System | 05 Sep 2020 12:53:58 |

US3222013

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:03:07

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | Amber Vasquez (b) (4) | 05 Sep 2020 12:53:58 |

US3222013

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:03:07

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'No (N)' | (b) (4) Amber Vasquez (b) (4) | 05 Sep 2020 12:53:58 |

US3222013

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:03:07

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered empty. | Amber Vasquez (b) (4) | 05 Sep 2020 12:53:58 |

US3222013

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User entered empty. | System | 05 Sep 2020 12:53:58 |

US3222013

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:07

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'Yes (Y)' | (b) (4) Amber Vasquez (b) (4) | 05 Sep 2020 12:54:03 |

US3222013

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:07

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User entered 'I' | System | 05 Sep 2020 12:54:03 |

US3222013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| Data entry locked. | System | 04 Sep 2020 19:55:59 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 04 Sep 2020 19:55:59 |

US3222013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-04T16:11:21', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'd4f5e50f-448e-44d4-821f-80d4549c0427' | System | 04 Sep 2020 20:11:55 |
| User entered 'Yes (Y)' | System | 04 Sep 2020 20:11:55 |

US3222013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-04T16:11:31', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'd4f5e50f-448e-44d4-821f-80d4549c0427' | System | 04 Sep 2020 20:11:55 |
| User entered '98.1' | System | 04 Sep 2020 20:11:55 |

US3222013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-04T16:11:42', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'd4f5e50f-448e-44d4-821f-80d4549c0427' | System | 04 Sep 2020 20:11:55 |
| User entered 'No (N)' | System | 04 Sep 2020 20:11:55 |

US3222013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-04T16:11:50', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'd4f5e50f-448e-44d4-821f-80d4549c0427' | System | 04 Sep 2020 20:11:55 |
| User entered '04 Sep 2020 16:11' | System | 04 Sep 2020 20:11:55 |

US3222013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| User entered '04 Sep 2020 15:57' | System | 04 Sep 2020 19:55:59 |

US3222013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| User entered '04 Sep 2020 18:27' | System | 04 Sep 2020 19:55:59 |

US3222013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| Data entry locked. | System | 04 Sep 2020 19:55:59 |
| User entered 'Day 1, after vaccination (at home)' | System | 04 Sep 2020 19:55:59 |

US3222013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-04T20:26:43', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '6e5eba61-7ca1-4b61-8793-addce0ed9b62' | System | 05 Sep 2020 00:28:57 |
| User entered 'Yes (Y)' | System | 05 Sep 2020 00:28:57 |

US3222013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-04T20:28:45', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '6e5eba61-7ca1-4b61-8793-addce0ed9b62' | System | 05 Sep 2020 00:28:57 |
| User entered '97.1' | System | 05 Sep 2020 00:28:57 |

US3222013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-04T20:28:50', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '6e5eba61-7ca1-4b61-8793-addce0ed9b62' | System | 05 Sep 2020 00:28:57 |
| User entered 'No (N)' | System | 05 Sep 2020 00:28:57 |

US3222013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-04T20:28:56', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '6e5eba61-7ca1-4b61-8793-addce0ed9b62' | System | 05 Sep 2020 00:28:57 |
| User entered '04 Sep 2020 20:28' | System | 05 Sep 2020 00:28:57 |

US3222013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| User entered '04 Sep 2020 19:22' | System | 04 Sep 2020 19:55:59 |

US3222013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| User entered '05 Sep 2020 11:59' | System | 04 Sep 2020 19:55:59 |

US3222013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| Data entry locked. | System | 04 Sep 2020 19:55:59 |
| User entered 'Day 2' | System | 04 Sep 2020 19:55:59 |

US3222013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:03:07

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-05T15:01:23', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'f92c1e02-a5c8-4292-8d74-716eb016b36d' | System | 05 Sep 2020 19:01:45 |
| User entered 'Yes (Y)' | System | 05 Sep 2020 19:01:45 |

US3222013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:03:07

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-05T15:01:29', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'f92c1e02-a5c8-4292-8d74-716eb016b36d' | System | 05 Sep 2020 19:01:45 |
| User entered '98.4' | System | 05 Sep 2020 19:01:45 |

US3222013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-05T15:01:35', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'f92c1e02-a5c8-4292-8d74-716eb016b36d' | System | 05 Sep 2020 19:01:45 |
| User entered 'No (N)' | System | 05 Sep 2020 19:01:45 |

US3222013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:03:07

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-05T15:01:42', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'f92c1e02-a5c8-4292-8d74-716eb016b36d' | System | 05 Sep 2020 19:01:45 |
| User entered '05 Sep 2020 15:01' | System | 05 Sep 2020 19:01:45 |

US3222013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:03:07

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| User entered '05 Sep 2020 12:00' | System | 04 Sep 2020 19:55:59 |

US3222013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:03:07

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| User entered '06 Sep 2020 11:59' | System | 04 Sep 2020 19:55:59 |

US3222013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| Data entry locked. | System | 04 Sep 2020 19:55:59 |
| User entered 'Day 3' | System | 04 Sep 2020 19:55:59 |

US3222013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:03:07

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-06T14:57:01', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'b711401f-0689-4d4e-9f6e-08eac1f36410' | System | 06 Sep 2020 18:57:49 |
| User entered 'Yes (Y)' | System | 06 Sep 2020 18:57:49 |

US3222013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:03:07

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-06T14:57:09', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'b711401f-0689-4d4e-9f6e-08eac1f36410' | System | 06 Sep 2020 18:57:49 |
| User entered '97.9' | System | 06 Sep 2020 18:57:49 |

US3222013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-06T14:57:41', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'b711401f-0689-4d4e-9f6e-08eac1f36410' | System | 06 Sep 2020 18:57:49 |
| User entered 'No (N)' | System | 06 Sep 2020 18:57:49 |

US3222013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:03:07

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-06T14:57:48', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'b711401f-0689-4d4e-9f6e-08eac1f36410' | System | 06 Sep 2020 18:57:49 |
| User entered '06 Sep 2020 14:57' | System | 06 Sep 2020 18:57:49 |

US3222013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:03:07

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| User entered '06 Sep 2020 12:00' | System | 04 Sep 2020 19:55:59 |

US3222013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:03:07

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| User entered '07 Sep 2020 11:59' | System | 04 Sep 2020 19:55:59 |

US3222013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| Data entry locked. | System | 04 Sep 2020 19:55:59 |
| User entered 'Day 4' | System | 04 Sep 2020 19:55:59 |

US3222013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:03:07

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-07T15:03:35', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'ca53ae3d-b87e-4930-b1ca-399aa9865a25' | System | 07 Sep 2020 19:04:18 |
| User entered 'Yes (Y)' | System | 07 Sep 2020 19:04:18 |

US3222013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:03:07

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-07T15:04:01', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'ca53ae3d-b87e-4930-b1ca-399aa9865a25' | System | 07 Sep 2020 19:04:18 |
| User entered '98.4' | System | 07 Sep 2020 19:04:18 |

US3222013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-07T15:04:08', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'ca53ae3d-b87e-4930-b1ca-399aa9865a25' | System | 07 Sep 2020 19:04:18 |
| User entered 'No (N)' | System | 07 Sep 2020 19:04:18 |

US3222013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:03:07

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-07T15:04:16', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'ca53ae3d-b87e-4930-b1ca-399aa9865a25' | System | 07 Sep 2020 19:04:18 |
| User entered '07 Sep 2020 15:04' | System | 07 Sep 2020 19:04:18 |

US3222013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:03:07

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| User entered '07 Sep 2020 12:00' | System | 04 Sep 2020 19:55:59 |

US3222013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:03:07

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| User entered '08 Sep 2020 11:59' | System | 04 Sep 2020 19:55:59 |

US3222013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| Data entry locked. | System | 04 Sep 2020 19:55:59 |
| User entered 'Day 5' | System | 04 Sep 2020 19:55:59 |

US3222013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:03:07

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-08T14:45:37', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '1858f2c8-f8bb-4880-ad59-78858d5a7797' | System | 08 Sep 2020 18:47:02 |
| User entered 'Yes (Y)' | System | 08 Sep 2020 18:47:02 |

US3222013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:03:07

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-08T14:46:48', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '1858f2c8-f8bb-4880-ad59-78858d5a7797' | System | 08 Sep 2020 18:47:02 |
| User entered '98.1' | System | 08 Sep 2020 18:47:02 |

US3222013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-08T14:46:53', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '1858f2c8-f8bb-4880-ad59-78858d5a7797' | System | 08 Sep 2020 18:47:02 |
| User entered 'No (N)' | System | 08 Sep 2020 18:47:02 |

US3222013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:03:07

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-08T14:46:58', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '1858f2c8-f8bb-4880-ad59-78858d5a7797' | System | 08 Sep 2020 18:47:02 |
| User entered '08 Sep 2020 14:46' | System | 08 Sep 2020 18:47:02 |

US3222013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:03:07

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| User entered '08 Sep 2020 12:00' | System | 04 Sep 2020 19:55:59 |

US3222013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:03:07

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| User entered '09 Sep 2020 11:59' | System | 04 Sep 2020 19:55:59 |

US3222013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| Data entry locked. | System | 04 Sep 2020 19:55:59 |
| User entered 'Day 6' | System | 04 Sep 2020 19:55:59 |

US3222013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:03:07

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-09T14:35:49', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'fe06b6d1-6ea9-47a5-8fe4-527067f7f1d4' | System | 09 Sep 2020 18:37:56 |
| User entered 'Yes (Y)' | System | 09 Sep 2020 18:37:56 |

US3222013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:03:07

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-09T14:37:41', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'fe06b6d1-6ea9-47a5-8fe4-527067f7f1d4' | System | 09 Sep 2020 18:37:56 |
| User entered '96.9' | System | 09 Sep 2020 18:37:56 |

US3222013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-09T14:37:44', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'fe06b6d1-6ea9-47a5-8fe4-527067f7f1d4' | System | 09 Sep 2020 18:37:56 |
| User entered 'No (N)' | System | 09 Sep 2020 18:37:56 |

US3222013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:03:07

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-09T14:37:52', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'fe06b6d1-6ea9-47a5-8fe4-527067f7f1d4' | System | 09 Sep 2020 18:37:56 |
| User entered '09 Sep 2020 14:37' | System | 09 Sep 2020 18:37:56 |

US3222013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:03:07

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| User entered '09 Sep 2020 12:00' | System | 04 Sep 2020 19:55:59 |

US3222013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:03:07

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| User entered '10 Sep 2020 11:59' | System | 04 Sep 2020 19:55:59 |

US3222013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| Data entry locked. | System | 04 Sep 2020 19:55:59 |
| User entered 'Day 7' | System | 04 Sep 2020 19:55:59 |

US3222013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:03:07

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-10T15:01:13', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'fb6b9af7-4c50-4af1-96f4-0642c196a37f' | System | 10 Sep 2020 19:02:26 |
| User entered 'Yes (Y)' | System | 10 Sep 2020 19:02:26 |

US3222013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:03:07

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-10T15:02:16', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'fb6b9af7-4c50-4af1-96f4-0642c196a37f' | System | 10 Sep 2020 19:02:26 |
| User entered '98.5' | System | 10 Sep 2020 19:02:26 |

US3222013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-10T15:02:19', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'fb6b9af7-4c50-4af1-96f4-0642c196a37f' | System | 10 Sep 2020 19:02:26 |
| User entered 'No (N)' | System | 10 Sep 2020 19:02:26 |

US3222013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:03:07

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-10T15:02:23', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'fb6b9af7-4c50-4af1-96f4-0642c196a37f' | System | 10 Sep 2020 19:02:26 |
| User entered '10 Sep 2020 15:02' | System | 10 Sep 2020 19:02:26 |

US3222013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:03:07

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| User entered '10 Sep 2020 12:00' | System | 04 Sep 2020 19:55:59 |

US3222013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:03:07

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| User entered '11 Sep 2020 11:59' | System | 04 Sep 2020 19:55:59 |

US3222013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| Data entry locked. | System | 04 Sep 2020 19:55:59 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 04 Sep 2020 19:55:59 |

US3222013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

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 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-04T16:13:55', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'a85d300a-8c17-4842-85b6-90e509602292' | System | 04 Sep 2020 20:14:17 |
| User entered 'None (1)' | System | 04 Sep 2020 20:14:17 |

US3222013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-04T16:13:58', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'a85d300a-8c17-4842-85b6-90e509602292' | System | 04 Sep 2020 20:14:17 |
| User entered 'No (N)' | System | 04 Sep 2020 20:14:17 |

US3222013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-04T16:14:02', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'a85d300a-8c17-4842-85b6-90e509602292' | System | 04 Sep 2020 20:14:17 |
| User entered 'No (N)' | System | 04 Sep 2020 20:14:17 |

US3222013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

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 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-04T16:14:06', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'a85d300a-8c17-4842-85b6-90e509602292' | System | 04 Sep 2020 20:14:17 |
| User entered 'None (1)' | System | 04 Sep 2020 20:14:17 |

US3222013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-04T16:14:12', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'a85d300a-8c17-4842-85b6-90e509602292' | System | 04 Sep 2020 20:14:17 |
| User entered '04 Sep 2020 16:14' | System | 04 Sep 2020 20:14:17 |

US3222013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| User entered '04 Sep 2020 15:57' | System | 04 Sep 2020 19:55:59 |

US3222013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| User entered '04 Sep 2020 18:27' | System | 04 Sep 2020 19:55:59 |

US3222013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| Data entry locked. | System | 04 Sep 2020 19:55:59 |
| User entered 'Day 1, after vaccination (at home)' | System | 04 Sep 2020 19:55:59 |

US3222013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

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 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-04T20:29:10', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '77e3b024-0c07-43d0-acc2-25658654c3ca' | System | 05 Sep 2020 00:29:32 |
| User entered 'None (1)' | System | 05 Sep 2020 00:29:32 |

US3222013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-04T20:29:14', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '77e3b024-0c07-43d0-acc2-25658654c3ca' | System | 05 Sep 2020 00:29:32 |
| User entered 'No (N)' | System | 05 Sep 2020 00:29:32 |

US3222013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-04T20:29:17', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '77e3b024-0c07-43d0-acc2-25658654c3ca' | System | 05 Sep 2020 00:29:32 |
| User entered 'No (N)' | System | 05 Sep 2020 00:29:32 |

US3222013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

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 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-04T20:29:22', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '77e3b024-0c07-43d0-acc2-25658654c3ca' | System | 05 Sep 2020 00:29:32 |
| User entered 'None (1)' | System | 05 Sep 2020 00:29:32 |

US3222013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-04T20:29:29', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '77e3b024-0c07-43d0-acc2-25658654c3ca' | System | 05 Sep 2020 00:29:32 |
| User entered '04 Sep 2020 20:29' | System | 05 Sep 2020 00:29:32 |

US3222013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| User entered '04 Sep 2020 19:22' | System | 04 Sep 2020 19:55:59 |

US3222013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| User entered '05 Sep 2020 11:59' | System | 04 Sep 2020 19:55:59 |

US3222013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| Data entry locked. | System | 04 Sep 2020 19:55:59 |
| User entered 'Day 2' | System | 04 Sep 2020 19:55:59 |

US3222013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:03:07

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 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-05T15:02:10', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '2483151f-7ae7-46e5-a50b-f6d5656d2943' | System | 05 Sep 2020 19:02:45 |
| User entered 'None (1)' | System | 05 Sep 2020 19:02:45 |

US3222013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:03:07

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-05T15:02:14', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '2483151f-7ae7-46e5-a50b-f6d5656d2943' | System | 05 Sep 2020 19:02:45 |
| User entered 'No (N)' | System | 05 Sep 2020 19:02:45 |

US3222013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-05T15:02:17', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '2483151f-7ae7-46e5-a50b-f6d5656d2943' | System | 05 Sep 2020 19:02:45 |
| User entered 'No (N)' | System | 05 Sep 2020 19:02:45 |

US3222013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:03:07

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 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-05T15:02:22', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '2483151f-7ae7-46e5-a50b-f6d5656d2943' | System | 05 Sep 2020 19:02:45 |
| User entered 'None (1)' | System | 05 Sep 2020 19:02:45 |

US3222013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:03:07

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-05T15:02:39', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '2483151f-7ae7-46e5-a50b-f6d5656d2943' | System | 05 Sep 2020 19:02:45 |
| User entered '05 Sep 2020 15:02' | System | 05 Sep 2020 19:02:45 |

US3222013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:03:07

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| User entered '05 Sep 2020 12:00' | System | 04 Sep 2020 19:55:59 |

US3222013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:03:07

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| User entered '06 Sep 2020 11:59' | System | 04 Sep 2020 19:55:59 |

US3222013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| Data entry locked. | System | 04 Sep 2020 19:55:59 |
| User entered 'Day 3' | System | 04 Sep 2020 19:55:59 |

US3222013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:03:07

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 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-06T14:57:56', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '4d451d28-8c87-4cd6-9c41-6fb338534206' | System | 06 Sep 2020 18:58:16 |
| User entered 'None (1)' | System | 06 Sep 2020 18:58:16 |

US3222013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:03:07

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-06T14:58:01', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '4d451d28-8c87-4cd6-9c41-6fb338534206' | System | 06 Sep 2020 18:58:16 |
| User entered 'No (N)' | System | 06 Sep 2020 18:58:16 |

US3222013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-06T14:58:05', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '4d451d28-8c87-4cd6-9c41-6fb338534206' | System | 06 Sep 2020 18:58:16 |
| User entered 'No (N)' | System | 06 Sep 2020 18:58:16 |

US3222013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:03:07

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 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-06T14:58:09', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '4d451d28-8c87-4cd6-9c41-6fb338534206' | System | 06 Sep 2020 18:58:16 |
| User entered 'None (1)' | System | 06 Sep 2020 18:58:16 |

US3222013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:03:07

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-06T14:58:14', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '4d451d28-8c87-4cd6-9c41-6fb338534206' | System | 06 Sep 2020 18:58:16 |
| User entered '06 Sep 2020 14:58' | System | 06 Sep 2020 18:58:16 |

US3222013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:03:07

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| User entered '06 Sep 2020 12:00' | System | 04 Sep 2020 19:55:59 |

US3222013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:03:07

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| User entered '07 Sep 2020 11:59' | System | 04 Sep 2020 19:55:59 |

US3222013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| Data entry locked. | System | 04 Sep 2020 19:55:59 |
| User entered 'Day 4' | System | 04 Sep 2020 19:55:59 |

US3222013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:03:07

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 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-07T15:04:23', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '16953b85-6657-4f7d-8df4-570bf1bb4771' | System | 07 Sep 2020 19:04:46 |
| User entered 'None (1)' | System | 07 Sep 2020 19:04:46 |

US3222013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-07T15:04:27', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '16953b85-6657-4f7d-8df4-570bf1bb4771' | System | 07 Sep 2020 19:04:46 |
| User entered 'No (N)' | System | 07 Sep 2020 19:04:46 |

US3222013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-07T15:04:32', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '16953b85-6657-4f7d-8df4-570bf1bb4771' | System | 07 Sep 2020 19:04:46 |
| User entered 'No (N)' | System | 07 Sep 2020 19:04:46 |

US3222013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:03:07

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 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-07T15:04:36', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '16953b85-6657-4f7d-8df4-570bf1bb4771' | System | 07 Sep 2020 19:04:46 |
| User entered 'None (1)' | System | 07 Sep 2020 19:04:46 |

US3222013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:03:07

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-07T15:04:44', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '16953b85-6657-4f7d-8df4-570bf1bb4771' | System | 07 Sep 2020 19:04:46 |
| User entered '07 Sep 2020 15:04' | System | 07 Sep 2020 19:04:46 |

US3222013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:03:07

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| User entered '07 Sep 2020 12:00' | System | 04 Sep 2020 19:55:59 |

US3222013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:03:07

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| User entered '08 Sep 2020 11:59' | System | 04 Sep 2020 19:55:59 |

US3222013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| Data entry locked. | System | 04 Sep 2020 19:55:59 |
| User entered 'Day 5' | System | 04 Sep 2020 19:55:59 |

US3222013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:03:07

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 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-08T14:47:05', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '1b2e52f9-5abf-4d8c-a939-f6af8d72cb36' | System | 08 Sep 2020 18:47:30 |
| User entered 'None (1)' | System | 08 Sep 2020 18:47:30 |

US3222013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-08T14:47:11', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '1b2e52f9-5abf-4d8c-a939-f6af8d72cb36' | System | 08 Sep 2020 18:47:30 |
| User entered 'No (N)' | System | 08 Sep 2020 18:47:30 |

US3222013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-08T14:47:15', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '1b2e52f9-5abf-4d8c-a939-f6af8d72cb36' | System | 08 Sep 2020 18:47:30 |
| User entered 'No (N)' | System | 08 Sep 2020 18:47:30 |

US3222013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:03:07

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 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-08T14:47:19', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '1b2e52f9-5abf-4d8c-a939-f6af8d72cb36' | System | 08 Sep 2020 18:47:30 |
| User entered 'None (1)' | System | 08 Sep 2020 18:47:30 |

US3222013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:03:07

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-08T14:47:27', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '1b2e52f9-5abf-4d8c-a939-f6af8d72cb36' | System | 08 Sep 2020 18:47:30 |
| User entered '08 Sep 2020 14:47' | System | 08 Sep 2020 18:47:30 |

US3222013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:03:07

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| User entered '08 Sep 2020 12:00' | System | 04 Sep 2020 19:55:59 |

US3222013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:03:07

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| User entered '09 Sep 2020 11:59' | System | 04 Sep 2020 19:55:59 |

US3222013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| Data entry locked. | System | 04 Sep 2020 19:55:59 |
| User entered 'Day 6' | System | 04 Sep 2020 19:55:59 |

US3222013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:03:07

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 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-09T14:38:00', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'ff4be8dd-9594-4f36-b0d4-badf02d280f2' | System | 09 Sep 2020 18:38:19 |
| User entered 'None (1)' | System | 09 Sep 2020 18:38:19 |

US3222013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-09T14:38:03', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'ff4be8dd-9594-4f36-b0d4-badf02d280f2' | System | 09 Sep 2020 18:38:19 |
| User entered 'No (N)' | System | 09 Sep 2020 18:38:19 |

US3222013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-09T14:38:07', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'ff4be8dd-9594-4f36-b0d4-badf02d280f2' | System | 09 Sep 2020 18:38:19 |
| User entered 'No (N)' | System | 09 Sep 2020 18:38:19 |

US3222013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:03:07

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 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-09T14:38:10', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'ff4be8dd-9594-4f36-b0d4-badf02d280f2' | System | 09 Sep 2020 18:38:19 |
| User entered 'None (1)' | System | 09 Sep 2020 18:38:19 |

US3222013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:03:07

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-09T14:38:15', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'ff4be8dd-9594-4f36-b0d4-badf02d280f2' | System | 09 Sep 2020 18:38:19 |
| User entered '09 Sep 2020 14:38' | System | 09 Sep 2020 18:38:19 |

US3222013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:03:07

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| User entered '09 Sep 2020 12:00' | System | 04 Sep 2020 19:55:59 |

US3222013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:03:07

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| User entered '10 Sep 2020 11:59' | System | 04 Sep 2020 19:55:59 |

US3222013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| Data entry locked. | System | 04 Sep 2020 19:55:59 |
| User entered 'Day 7' | System | 04 Sep 2020 19:55:59 |

US3222013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:03:07

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 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-10T15:02:28', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'b91c0399-6ea7-414e-a520-dbadba265326' | System | 10 Sep 2020 19:03:07 |
| User entered 'None (1)' | System | 10 Sep 2020 19:03:07 |

US3222013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:03:07

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-10T15:02:32', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'b91c0399-6ea7-414e-a520-dbadba265326' | System | 10 Sep 2020 19:03:07 |
| User entered 'No (N)' | System | 10 Sep 2020 19:03:07 |

US3222013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-10T15:02:36', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'b91c0399-6ea7-414e-a520-dbadba265326' | System | 10 Sep 2020 19:03:07 |
| User entered 'No (N)' | System | 10 Sep 2020 19:03:07 |

US3222013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:03:07

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 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-10T15:02:40', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'b91c0399-6ea7-414e-a520-dbadba265326' | System | 10 Sep 2020 19:03:07 |
| User entered 'None (1)' | System | 10 Sep 2020 19:03:07 |

US3222013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:03:07

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-10T15:02:44', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'b91c0399-6ea7-414e-a520-dbadba265326' | System | 10 Sep 2020 19:03:07 |
| User entered '10 Sep 2020 15:02' | System | 10 Sep 2020 19:03:07 |

US3222013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:03:07

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| User entered '10 Sep 2020 12:00' | System | 04 Sep 2020 19:55:59 |

US3222013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:03:07

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| User entered '11 Sep 2020 11:59' | System | 04 Sep 2020 19:55:59 |

US3222013

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| Data entry locked. | System | 04 Sep 2020 19:55:59 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 04 Sep 2020 19:55:59 |

US3222013

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-04T17:13:14', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'b1c0773b-6a4e-484f-b507-169c8831eefe' | System | 04 Sep 2020 21:13:54 |
| User entered 'None (0)' | System | 04 Sep 2020 21:13:54 |

US3222013

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-04T17:13:18', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'b1c0773b-6a4e-484f-b507-169c8831eefe' | System | 04 Sep 2020 21:13:54 |
| User entered 'None (0)' | System | 04 Sep 2020 21:13:54 |

US3222013

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-04T17:13:22', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'b1c0773b-6a4e-484f-b507-169c8831eefe' | System | 04 Sep 2020 21:13:54 |
| User entered 'None (0)' | System | 04 Sep 2020 21:13:54 |

US3222013

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-04T17:13:29', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'b1c0773b-6a4e-484f-b507-169c8831eefe' | System | 04 Sep 2020 21:13:54 |
| User entered 'None (0)' | System | 04 Sep 2020 21:13:54 |

US3222013

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-04T17:13:32', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'b1c0773b-6a4e-484f-b507-169c8831eefe' | System | 04 Sep 2020 21:13:54 |
| User entered 'None (0)' | System | 04 Sep 2020 21:13:54 |

US3222013

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-04T17:13:35', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'b1c0773b-6a4e-484f-b507-169c8831eefe' | System | 04 Sep 2020 21:13:54 |
| User entered 'None (0)' | System | 04 Sep 2020 21:13:54 |

US3222013

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

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 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-04T17:13:45', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'b1c0773b-6a4e-484f-b507-169c8831eefe' | System | 04 Sep 2020 21:13:54 |
| User entered 'No (N)' | System | 04 Sep 2020 21:13:54 |

US3222013

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-04T17:13:52', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'b1c0773b-6a4e-484f-b507-169c8831eefe' | System | 04 Sep 2020 21:13:54 |
| User entered '04 Sep 2020 17:13' | System | 04 Sep 2020 21:13:54 |

US3222013

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| User entered '04 Sep 2020 15:57' | System | 04 Sep 2020 19:55:59 |

US3222013

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:03:07

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| User entered '04 Sep 2020 18:27' | System | 04 Sep 2020 19:55:59 |

US3222013

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| Data entry locked. | System | 04 Sep 2020 19:55:59 |
| User entered 'Day 1, after vaccination (at home)' | System | 04 Sep 2020 19:55:59 |

US3222013

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-04T20:29:37', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'be06ce1a-76a7-4c8a-aba4-3b3873f61a41' | System | 05 Sep 2020 00:30:14 |
| User entered 'None (0)' | System | 05 Sep 2020 00:30:14 |

US3222013

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-04T20:29:40', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'be06ce1a-76a7-4c8a-aba4-3b3873f61a41' | System | 05 Sep 2020 00:30:14 |
| User entered 'None (0)' | System | 05 Sep 2020 00:30:14 |

US3222013

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-04T20:29:43', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'be06ce1a-76a7-4c8a-aba4-3b3873f61a41' | System | 05 Sep 2020 00:30:14 |
| User entered 'None (0)' | System | 05 Sep 2020 00:30:14 |

US3222013

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-04T20:29:47', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'be06ce1a-76a7-4c8a-aba4-3b3873f61a41' | System | 05 Sep 2020 00:30:14 |
| User entered 'None (0)' | System | 05 Sep 2020 00:30:14 |

US3222013

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-04T20:29:50', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'be06ce1a-76a7-4c8a-aba4-3b3873f61a41' | System | 05 Sep 2020 00:30:14 |
| User entered 'None (0)' | System | 05 Sep 2020 00:30:14 |

US3222013

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-04T20:29:54', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'be06ce1a-76a7-4c8a-aba4-3b3873f61a41' | System | 05 Sep 2020 00:30:14 |
| User entered 'None (0)' | System | 05 Sep 2020 00:30:14 |

US3222013

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

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 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-04T20:30:07', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'be06ce1a-76a7-4c8a-aba4-3b3873f61a41' | System | 05 Sep 2020 00:30:14 |
| User entered 'No (N)' | System | 05 Sep 2020 00:30:14 |

US3222013

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-04T20:30:12', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'be06ce1a-76a7-4c8a-aba4-3b3873f61a41' | System | 05 Sep 2020 00:30:14 |
| User entered '04 Sep 2020 20:30' | System | 05 Sep 2020 00:30:14 |

US3222013

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| User entered '04 Sep 2020 19:22' | System | 04 Sep 2020 19:55:59 |

US3222013

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:03:07

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| User entered '05 Sep 2020 11:59' | System | 04 Sep 2020 19:55:59 |

US3222013

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| Data entry locked. | System | 04 Sep 2020 19:55:59 |
| User entered 'Day 2' | System | 04 Sep 2020 19:55:59 |

US3222013

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:03:07

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-05T15:02:45', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '5864a3a8-13d5-443d-8a2f-d37b89160c0a' | System | 05 Sep 2020 19:03:34 |
| User entered 'None (0)' | System | 05 Sep 2020 19:03:34 |

US3222013

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:03:07

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-05T15:02:48', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '5864a3a8-13d5-443d-8a2f-d37b89160c0a' | System | 05 Sep 2020 19:03:34 |
| User entered 'None (0)' | System | 05 Sep 2020 19:03:34 |

US3222013

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:03:07

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-05T15:02:53', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '5864a3a8-13d5-443d-8a2f-d37b89160c0a' | System | 05 Sep 2020 19:03:34 |
| User entered 'None (0)' | System | 05 Sep 2020 19:03:34 |

US3222013

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:03:07

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-05T15:02:57', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '5864a3a8-13d5-443d-8a2f-d37b89160c0a' | System | 05 Sep 2020 19:03:34 |
| User entered 'None (0)' | System | 05 Sep 2020 19:03:34 |

US3222013

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:03:07

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-05T15:03:01', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '5864a3a8-13d5-443d-8a2f-d37b89160c0a' | System | 05 Sep 2020 19:03:34 |
| User entered 'None (0)' | System | 05 Sep 2020 19:03:34 |

US3222013

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:03:07

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-05T15:03:13', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '5864a3a8-13d5-443d-8a2f-d37b89160c0a' | System | 05 Sep 2020 19:03:34 |
| User entered 'None (0)' | System | 05 Sep 2020 19:03:34 |

US3222013

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:03:07

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 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-05T15:03:20', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '5864a3a8-13d5-443d-8a2f-d37b89160c0a' | System | 05 Sep 2020 19:03:34 |
| User entered 'No (N)' | System | 05 Sep 2020 19:03:34 |

US3222013

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:03:07

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-05T15:03:30', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '5864a3a8-13d5-443d-8a2f-d37b89160c0a' | System | 05 Sep 2020 19:03:34 |
| User entered '05 Sep 2020 15:03' | System | 05 Sep 2020 19:03:34 |

US3222013

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:03:07

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| User entered '05 Sep 2020 12:00' | System | 04 Sep 2020 19:55:59 |

US3222013

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:03:07

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| User entered '06 Sep 2020 11:59' | System | 04 Sep 2020 19:55:59 |

US3222013

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| Data entry locked. | System | 04 Sep 2020 19:55:59 |
| User entered 'Day 3' | System | 04 Sep 2020 19:55:59 |

US3222013

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:03:07

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-06T14:58:20', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '10ce4088-1a88-4a0d-b23b-d16f58a5c1cc' | System | 06 Sep 2020 18:58:55 |
| User entered 'None (0)' | System | 06 Sep 2020 18:58:55 |

US3222013

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:03:07

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-06T14:58:24', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '10ce4088-1a88-4a0d-b23b-d16f58a5c1cc' | System | 06 Sep 2020 18:58:55 |
| User entered 'None (0)' | System | 06 Sep 2020 18:58:55 |

US3222013

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:03:07

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-06T14:58:27', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '10ce4088-1a88-4a0d-b23b-d16f58a5c1cc' | System | 06 Sep 2020 18:58:55 |
| User entered 'None (0)' | System | 06 Sep 2020 18:58:55 |

US3222013

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:03:07

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-06T14:58:30', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '10ce4088-1a88-4a0d-b23b-d16f58a5c1cc' | System | 06 Sep 2020 18:58:55 |
| User entered 'None (0)' | System | 06 Sep 2020 18:58:55 |

US3222013

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:03:07

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-06T14:58:34', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '10ce4088-1a88-4a0d-b23b-d16f58a5c1cc' | System | 06 Sep 2020 18:58:55 |
| User entered 'None (0)' | System | 06 Sep 2020 18:58:55 |

US3222013

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:03:07

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-06T14:58:38', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '10ce4088-1a88-4a0d-b23b-d16f58a5c1cc' | System | 06 Sep 2020 18:58:55 |
| User entered 'None (0)' | System | 06 Sep 2020 18:58:55 |

US3222013

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:03:07

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 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-06T14:58:43', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '10ce4088-1a88-4a0d-b23b-d16f58a5c1cc' | System | 06 Sep 2020 18:58:55 |
| User entered 'No (N)' | System | 06 Sep 2020 18:58:55 |

US3222013

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:03:07

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-06T14:58:53', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '10ce4088-1a88-4a0d-b23b-d16f58a5c1cc' | System | 06 Sep 2020 18:58:55 |
| User entered '06 Sep 2020 14:58' | System | 06 Sep 2020 18:58:55 |

US3222013

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:03:07

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| User entered '06 Sep 2020 12:00' | System | 04 Sep 2020 19:55:59 |

US3222013

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:03:07

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| User entered '07 Sep 2020 11:59' | System | 04 Sep 2020 19:55:59 |

US3222013

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| Data entry locked. | System | 04 Sep 2020 19:55:59 |
| User entered 'Day 4' | System | 04 Sep 2020 19:55:59 |

US3222013

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:03:07

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-07T15:04:50', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'fb4fdfaa-6959-486f-8d71-669f18447d1c' | System | 07 Sep 2020 19:05:30 |
| User entered 'None (0)' | System | 07 Sep 2020 19:05:30 |

US3222013

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:03:07

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-07T15:04:55', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'fb4fdfaa-6959-486f-8d71-669f18447d1c' | System | 07 Sep 2020 19:05:30 |
| User entered 'None (0)' | System | 07 Sep 2020 19:05:30 |

US3222013

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:03:07

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-07T15:04:58', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'fb4fdfaa-6959-486f-8d71-669f18447d1c' | System | 07 Sep 2020 19:05:30 |
| User entered 'None (0)' | System | 07 Sep 2020 19:05:30 |

US3222013

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:03:07

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-07T15:05:02', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'fb4fdfaa-6959-486f-8d71-669f18447d1c' | System | 07 Sep 2020 19:05:30 |
| User entered 'None (0)' | System | 07 Sep 2020 19:05:30 |

US3222013

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:03:07

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-07T15:05:06', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'fb4fdfaa-6959-486f-8d71-669f18447d1c' | System | 07 Sep 2020 19:05:30 |
| User entered 'None (0)' | System | 07 Sep 2020 19:05:30 |

US3222013

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:03:07

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-07T15:05:13', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'fb4fdfaa-6959-486f-8d71-669f18447d1c' | System | 07 Sep 2020 19:05:30 |
| User entered 'None (0)' | System | 07 Sep 2020 19:05:30 |

US3222013

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:03:07

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 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-07T15:05:19', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'fb4fdfaa-6959-486f-8d71-669f18447d1c' | System | 07 Sep 2020 19:05:30 |
| User entered 'No (N)' | System | 07 Sep 2020 19:05:30 |

US3222013

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:03:07

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-07T15:05:29', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'fb4fdfaa-6959-486f-8d71-669f18447d1c' | System | 07 Sep 2020 19:05:30 |
| User entered '07 Sep 2020 15:05' | System | 07 Sep 2020 19:05:30 |

US3222013

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:03:07

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| User entered '07 Sep 2020 12:00' | System | 04 Sep 2020 19:55:59 |

US3222013

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:03:07

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| User entered '08 Sep 2020 11:59' | System | 04 Sep 2020 19:55:59 |

US3222013

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| Data entry locked. | System | 04 Sep 2020 19:55:59 |
| User entered 'Day 5' | System | 04 Sep 2020 19:55:59 |

US3222013

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:03:07

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-08T14:47:32', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '2cbcb51d-c1ea-4cb3-950b-cd6b64ecae1e' | System | 08 Sep 2020 18:48:05 |
| User entered 'None (0)' | System | 08 Sep 2020 18:48:05 |

US3222013

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:03:07

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-08T14:47:35', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '2cbcb51d-c1ea-4cb3-950b-cd6b64ecae1e' | System | 08 Sep 2020 18:48:05 |
| User entered 'None (0)' | System | 08 Sep 2020 18:48:05 |

US3222013

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:03:07

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-08T14:47:39', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '2cbcb51d-c1ea-4cb3-950b-cd6b64ecae1e' | System | 08 Sep 2020 18:48:05 |
| User entered 'None (0)' | System | 08 Sep 2020 18:48:05 |

US3222013

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:03:07

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-08T14:47:42', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '2cbcb51d-c1ea-4cb3-950b-cd6b64ecae1e' | System | 08 Sep 2020 18:48:05 |
| User entered 'None (0)' | System | 08 Sep 2020 18:48:05 |

US3222013

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:03:07

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-08T14:47:45', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '2cbcb51d-c1ea-4cb3-950b-cd6b64ecae1e' | System | 08 Sep 2020 18:48:05 |
| User entered 'None (0)' | System | 08 Sep 2020 18:48:05 |

US3222013

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:03:07

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-08T14:47:48', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '2cbcb51d-c1ea-4cb3-950b-cd6b64ecae1e' | System | 08 Sep 2020 18:48:05 |
| User entered 'None (0)' | System | 08 Sep 2020 18:48:05 |

US3222013

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:03:07

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 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-08T14:47:51', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '2cbcb51d-c1ea-4cb3-950b-cd6b64ecae1e' | System | 08 Sep 2020 18:48:05 |
| User entered 'No (N)' | System | 08 Sep 2020 18:48:05 |

US3222013

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:03:07

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-08T14:48:00', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '2cbcb51d-c1ea-4cb3-950b-cd6b64ecae1e' | System | 08 Sep 2020 18:48:05 |
| User entered '08 Sep 2020 14:48' | System | 08 Sep 2020 18:48:05 |

US3222013

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:03:07

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| User entered '08 Sep 2020 12:00' | System | 04 Sep 2020 19:55:59 |

US3222013

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:03:07

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| User entered '09 Sep 2020 11:59' | System | 04 Sep 2020 19:55:59 |

US3222013

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| Data entry locked. | System | 04 Sep 2020 19:55:59 |
| User entered 'Day 6' | System | 04 Sep 2020 19:55:59 |

US3222013

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:03:07

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-09T14:38:21', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'f32644d4-1688-4d7a-9ede-0adf4aadb65c' | System | 09 Sep 2020 18:38:57 |
| User entered 'None (0)' | System | 09 Sep 2020 18:38:57 |

US3222013

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:03:07

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-09T14:38:26', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'f32644d4-1688-4d7a-9ede-0adf4aadb65c' | System | 09 Sep 2020 18:38:57 |
| User entered 'None (0)' | System | 09 Sep 2020 18:38:57 |

US3222013

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:03:07

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-09T14:38:30', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'f32644d4-1688-4d7a-9ede-0adf4aadb65c' | System | 09 Sep 2020 18:38:57 |
| User entered 'None (0)' | System | 09 Sep 2020 18:38:57 |

US3222013

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:03:07

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-09T14:38:33', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'f32644d4-1688-4d7a-9ede-0adf4aadb65c' | System | 09 Sep 2020 18:38:57 |
| User entered 'None (0)' | System | 09 Sep 2020 18:38:57 |

US3222013

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:03:07

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-09T14:38:36', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'f32644d4-1688-4d7a-9ede-0adf4aadb65c' | System | 09 Sep 2020 18:38:57 |
| User entered 'None (0)' | System | 09 Sep 2020 18:38:57 |

US3222013

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:03:07

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-09T14:38:39', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'f32644d4-1688-4d7a-9ede-0adf4aadb65c' | System | 09 Sep 2020 18:38:57 |
| User entered 'None (0)' | System | 09 Sep 2020 18:38:57 |

US3222013

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:03:07

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 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-09T14:38:43', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'f32644d4-1688-4d7a-9ede-0adf4aadb65c' | System | 09 Sep 2020 18:38:57 |
| User entered 'No (N)' | System | 09 Sep 2020 18:38:57 |

US3222013

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:03:07

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-09T14:38:55', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'f32644d4-1688-4d7a-9ede-0adf4aadb65c' | System | 09 Sep 2020 18:38:57 |
| User entered '09 Sep 2020 14:38' | System | 09 Sep 2020 18:38:57 |

US3222013

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:03:07

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| User entered '09 Sep 2020 12:00' | System | 04 Sep 2020 19:55:59 |

US3222013

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:03:07

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| User entered '10 Sep 2020 11:59' | System | 04 Sep 2020 19:55:59 |

US3222013

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| Data entry locked. | System | 04 Sep 2020 19:55:59 |
| User entered 'Day 7' | System | 04 Sep 2020 19:55:59 |

US3222013

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:03:07

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-10T15:02:49', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '34006778-4cab-44a2-ad6d-aac469d3e64c' | System | 10 Sep 2020 19:03:57 |
| User entered 'None (0)' | System | 10 Sep 2020 19:03:57 |

US3222013

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:03:07

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-10T15:02:53', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '34006778-4cab-44a2-ad6d-aac469d3e64c' | System | 10 Sep 2020 19:03:57 |
| User entered 'None (0)' | System | 10 Sep 2020 19:03:57 |

US3222013

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:03:07

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-10T15:02:56', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '34006778-4cab-44a2-ad6d-aac469d3e64c' | System | 10 Sep 2020 19:03:57 |
| User entered 'None (0)' | System | 10 Sep 2020 19:03:57 |

US3222013

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:03:07

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-10T15:03:06', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '34006778-4cab-44a2-ad6d-aac469d3e64c' | System | 10 Sep 2020 19:03:57 |
| User entered 'None (0)' | System | 10 Sep 2020 19:03:57 |

US3222013

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:03:07

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-10T15:03:09', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '34006778-4cab-44a2-ad6d-aac469d3e64c' | System | 10 Sep 2020 19:03:57 |
| User entered 'None (0)' | System | 10 Sep 2020 19:03:57 |

US3222013

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:03:07

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-10T15:03:13', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '34006778-4cab-44a2-ad6d-aac469d3e64c' | System | 10 Sep 2020 19:03:57 |
| User entered 'None (0)' | System | 10 Sep 2020 19:03:57 |

US3222013

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:03:07

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 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-10T15:03:17', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '34006778-4cab-44a2-ad6d-aac469d3e64c' | System | 10 Sep 2020 19:03:57 |
| User entered 'No (N)' | System | 10 Sep 2020 19:03:57 |

US3222013

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:03:07

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-09-10T15:03:22', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '34006778-4cab-44a2-ad6d-aac469d3e64c' | System | 10 Sep 2020 19:03:57 |
| User entered '10 Sep 2020 15:03' | System | 10 Sep 2020 19:03:57 |

US3222013

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:03:07

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| User entered '10 Sep 2020 12:00' | System | 04 Sep 2020 19:55:59 |

US3222013

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:03:07

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| User entered '11 Sep 2020 11:59' | System | 04 Sep 2020 19:55:59 |

US3222013

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:07

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'Yes (Y)' | Albert Garcia (b) (4) | 05 Oct 2020 18:25:34 |

US3222013

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered '11 Sep 2020' | Albert Garcia (b) (4) | 05 Oct 2020 18:25:34 |

US3222013

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:07

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'Contact Made (CONTACT MADE)' | Albert Garcia (b) (4) | 05 Oct 2020 18:25:34 |

US3222013

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:07

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered empty. | Albert Garcia (b) (4) | 05 Oct 2020 18:25:34 |

US3222013

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:07

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'Yes (Y)' | Albert Garcia (b) (4) | 05 Oct 2020 18:25:41 |

US3222013

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:07

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User entered 'I' | System | 05 Oct 2020 18:25:41 |

US3222013

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:07

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'Yes (Y)' | Albert Garcia (b) (4) | 13 Oct 2020 13:39:43 |

US3222013

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered '18 Sep 2020' | Albert Garcia (b) (4) | 13 Oct 2020 13:39:43 |

US3222013

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:07

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) Albert Garcia (b) (4) | 13 Oct 2020 13:39:43 |

US3222013

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:07

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered empty. | Albert Garcia (b) (4) | 13 Oct 2020 13:39:43 |

US3222013

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:07

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'Yes (Y)' | Albert Garcia (b) (4) | 05 Oct 2020 18:25:47 |

US3222013

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:07

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User entered 'I' | System | 05 Oct 2020 18:25:47 |

US3222013

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:07

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'Yes (Y)' | Albert Garcia (b) (4) | 13 Oct 2020 13:39:58 |

US3222013

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered '25 Sep 2020' | Albert Garcia (b) (4) | 13 Oct 2020 13:39:58 |

US3222013

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:07

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'Contact Made (CONTACT MADE)' | Albert Garcia (b) (4) | 13 Oct 2020 13:39:58 |

US3222013

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:07

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered empty. | Albert Garcia (b) (4) | 13 Oct 2020 13:39:58 |

US3222013

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:07

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'Yes (Y)' | Albert Garcia (b) (4) | 05 Oct 2020 18:25:55 |

US3222013

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:07

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User entered 'I' | System | 05 Oct 2020 18:25:55 |

US3222013

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:03:07

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'Yes (Y)' | Albert Garcia (b) (4) | 05 Oct 2020 18:26:15 |

US3222013

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered '2 Oct 2020' | Albert Garcia (b) (4) | 05 Oct 2020 18:26:15 |

US3222013

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'Clinic (Clinic)' | Albert Garcia (b) (4) | 05 Oct 2020 18:26:15 |

US3222013

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:03:07

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User entered 'VISIT3' | System | 05 Oct 2020 18:26:15 |

US3222013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:07

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'No (N)' | Albert Garcia (b) (4) | 05 Oct 2020 18:26:25 |

US3222013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:07

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered empty. | Albert Garcia (b) (4) | 05 Oct 2020 18:26:25 |

US3222013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered empty. | Albert Garcia (b) (4) | 05 Oct 2020 18:26:25 |

US3222013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User entered empty. | System | 05 Oct 2020 18:26:25 |

US3222013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:07

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered empty. | Albert Garcia (b) (4) | 05 Oct 2020 18:26:25 |

US3222013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:07

[Route of measurement](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered empty. | Albert Garcia (b) (4) | 05 Oct 2020 18:26:25 |

US3222013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:07

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered empty. | Albert Garcia (b) (4) | 05 Oct 2020 18:26:25 |

US3222013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:07

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered empty. | Albert Garcia (b) (4) | 05 Oct 2020 18:26:25 |

US3222013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:07

[Pulse units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User entered empty. | System | 05 Oct 2020 18:26:25 |

US3222013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered empty. | Albert Garcia (b) (4) | 05 Oct 2020 18:26:25 |

US3222013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:07

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User entered empty. | System | 05 Oct 2020 18:26:25 |

US3222013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:07

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered empty. | Albert Garcia (b) (4) | 05 Oct 2020 18:26:25 |

US3222013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:07

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User entered empty. | System | 05 Oct 2020 18:26:25 |

US3222013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:07

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered empty. | Albert Garcia (b) (4) | 05 Oct 2020 18:26:25 |

US3222013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:07

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User entered empty. | System | 05 Oct 2020 18:26:25 |

US3222013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:07

[Height \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| | | |

US3222013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:07

Weight (derived)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| | | |

US3222013

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:03:07

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'No (N)' | Albert Garcia (b) (4) | 05 Oct 2020 18:26:32 |

US3222013

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:03:07

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered empty. | Albert Garcia (b) (4) | 05 Oct 2020 18:26:32 |

US3222013

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:03:07

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'Yes (Y)' | Albert Garcia (b) (4) | 05 Oct 2020 18:26:41 |

US3222013

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:03:07

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered '2 Oct 2020' | Albert Garcia (b) (4) | 05 Oct 2020 18:26:41 |

US3222013

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:03:07

Collection time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered '12:55' | Albert Garcia (b) (4) | 05 Oct 2020 18:26:41 |

US3222013

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User entered '2 Oct 2020 12:55' | System | 05 Oct 2020 18:26:41 |

US3222013

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:07

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'Yes (Y)' | Albert Garcia (b) (4) | 05 Oct 2020 18:26:44 |

US3222013

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:07

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User entered 'I' | System | 05 Oct 2020 18:26:44 |

US3222013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 06:14:41 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 14:51:53 |
| Data entry locked. | System | 06 Aug 2020 18:45:15 |
| User entered 'Day 64' | System | 06 Aug 2020 18:45:15 |

US3222013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[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) | 25 Apr 2021 06:14:41 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

Have you been exposed to someone with 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) | 25 Apr 2021 06:14:41 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Please 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) | 25 Apr 2021 06:14:41 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[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) | 25 Apr 2021 06:14:41 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

Fever (Temperature \geq 100.4°F/38°C)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 06:14:41 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Chills](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 06:14:41 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Cough](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 06:14:41 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Shortness of breath](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 06:14:41 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Difficulty breathing](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 06:14:41 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Fatigue](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 06:14:41 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Muscle aches](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 06:14:41 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Body aches](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 06:14:41 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Headache](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 06:14:41 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[New loss of taste](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 06:14:41 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[New loss of smell](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 06:14:41 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Sore throat](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 06:14:41 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Congestion](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 06:14:41 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Runny nose](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 06:14:41 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Nausea](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 06:14:41 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Vomiting](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 06:14:41 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Diarrhea](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 06:14:41 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Please 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) | 25 Apr 2021 06:14:41 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[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) | 25 Apr 2021 06:14:41 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Please 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) | 25 Apr 2021 06:14:41 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 06:14:41 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 06:14:41 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 14:51:53 |
| Data entry locked. | System | 06 Aug 2020 18:45:15 |
| User entered '06 Oct 2020 00:01' | System | 06 Aug 2020 18:45:15 |

US3222013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 06:14:41 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 14:51:53 |
| Data entry locked. | System | 06 Aug 2020 18:45:15 |
| User entered '10 Oct 2020 23:59' | System | 06 Aug 2020 18:45:15 |

US3222013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 06:14:41 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 14:51:53 |
| Data entry locked. | System | 06 Aug 2020 18:45:15 |
| User entered 'Day 71' | System | 06 Aug 2020 18:45:15 |

US3222013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[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) | 25 Apr 2021 06:14:41 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

Have you been exposed to someone with 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) | 25 Apr 2021 06:14:41 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Please 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) | 25 Apr 2021 06:14:41 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[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) | 25 Apr 2021 06:14:41 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

Fever (Temperature \geq 100.4°F/38°C)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 06:14:41 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Chills](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 06:14:41 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Cough](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 06:14:41 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Shortness of breath](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 06:14:41 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Difficulty breathing](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 06:14:41 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Fatigue](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 06:14:41 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Muscle aches](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 06:14:41 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Body aches](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 06:14:41 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Headache](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 06:14:41 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[New loss of taste](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 06:14:41 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[New loss of smell](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 06:14:41 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Sore throat](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 06:14:41 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Congestion](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 06:14:41 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Runny nose](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 06:14:41 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Nausea](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 06:14:41 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Vomiting](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 06:14:41 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Diarrhea](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 06:14:41 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Please 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) | 25 Apr 2021 06:14:41 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[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) | 25 Apr 2021 06:14:41 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Please 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) | 25 Apr 2021 06:14:41 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 06:14:41 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 06:14:41 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 14:51:53 |
| Data entry locked. | System | 06 Aug 2020 18:45:15 |
| User entered '13 Oct 2020 00:01' | System | 06 Aug 2020 18:45:15 |

US3222013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 06:14:41 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 14:51:53 |
| Data entry locked. | System | 06 Aug 2020 18:45:15 |
| User entered '17 Oct 2020 23:59' | System | 06 Aug 2020 18:45:15 |

US3222013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| Data entry locked. | System | 06 Aug 2020 18:45:15 |
| User entered 'Day 78' | System | 06 Aug 2020 18:45:15 |

US3222013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[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 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-10-23T09:50:33', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '04ca1174-643f-49ad-8984-c722f4447e48' | System | 23 Oct 2020 13:50:54 |
| User entered 'No (N)' | System | 23 Oct 2020 13:50:54 |

US3222013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

Have you been exposed to someone with 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 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-10-23T09:50:40', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '04ca1174-643f-49ad-8984-c722f4447e48' | System | 23 Oct 2020 13:50:54 |
| User entered 'No (N)' | System | 23 Oct 2020 13:50:54 |

US3222013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-10-23T09:50:52', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '04ca1174-643f-49ad-8984-c722f4447e48' | System | 23 Oct 2020 13:50:54 |
| User entered '23 Oct 2020 09:50:52' | System | 23 Oct 2020 13:50:54 |

US3222013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| Data entry locked. | System | 06 Aug 2020 18:45:15 |
| User entered '20 Oct 2020 00:01' | System | 06 Aug 2020 18:45:15 |

US3222013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| Data entry locked. | System | 06 Aug 2020 18:45:15 |
| User entered '24 Oct 2020 23:59' | System | 06 Aug 2020 18:45:15 |

US3222013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| Data entry locked. | System | 06 Aug 2020 18:45:15 |
| User entered 'Day 92' | System | 06 Aug 2020 18:45:15 |

US3222013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[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 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-11-03T10:06:23', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '9a5f0fa7-9a6d-4ec5-b5c7-a8bf8aa4bbc5' | System | 03 Nov 2020 15:06:45 |
| User entered 'No (N)' | System | 03 Nov 2020 15:06:45 |

US3222013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

Have you been exposed to someone with 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 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-11-03T10:06:29', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '9a5f0fa7-9a6d-4ec5-b5c7-a8bf8aa4bbc5' | System | 03 Nov 2020 15:06:45 |
| User entered 'No (N)' | System | 03 Nov 2020 15:06:45 |

US3222013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-11-03T10:06:42', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '9a5f0fa7-9a6d-4ec5-b5c7-a8bf8aa4bbc5' | System | 03 Nov 2020 15:06:45 |
| User entered '03 Nov 2020 10:06:42' | System | 03 Nov 2020 15:06:45 |

US3222013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| Data entry locked. | System | 06 Aug 2020 18:45:15 |
| User entered '03 Nov 2020 00:01' | System | 06 Aug 2020 18:45:15 |

US3222013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| Data entry locked. | System | 06 Aug 2020 18:45:15 |
| User entered '07 Nov 2020 23:59' | System | 06 Aug 2020 18:45:15 |

US3222013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| Data entry locked. | System | 06 Aug 2020 18:45:15 |
| User entered 'Day 99' | System | 06 Aug 2020 18:45:15 |

US3222013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[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 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-11-10T09:07:41', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'cbd2dd07-a74d-4cf0-ab64-d22cd4145488' | System | 10 Nov 2020 14:08:05 |
| User entered 'No (N)' | System | 10 Nov 2020 14:08:05 |

US3222013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

Have you been exposed to someone with 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 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-11-10T09:07:49', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'cbd2dd07-a74d-4cf0-ab64-d22cd4145488' | System | 10 Nov 2020 14:08:05 |
| User entered 'No (N)' | System | 10 Nov 2020 14:08:05 |

US3222013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-11-10T09:07:58', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'cbd2dd07-a74d-4cf0-ab64-d22cd4145488' | System | 10 Nov 2020 14:08:05 |
| User entered '10 Nov 2020 09:07:58' | System | 10 Nov 2020 14:08:05 |

US3222013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| Data entry locked. | System | 06 Aug 2020 18:45:15 |
| User entered '10 Nov 2020 00:01' | System | 06 Aug 2020 18:45:15 |

US3222013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| Data entry locked. | System | 06 Aug 2020 18:45:15 |
| User entered '14 Nov 2020 23:59' | System | 06 Aug 2020 18:45:15 |

US3222013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| Data entry locked. | System | 06 Aug 2020 18:45:15 |
| User entered 'Day 106' | System | 06 Aug 2020 18:45:15 |

US3222013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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 00:40:33 |
| Query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' canceled (Site from DM). | (b) (4), (b) (6) | 27 Feb 2021 03:47:24 |
| User opened query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM). | (b) (4), (b) (6) | 27 Feb 2021 03:46:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-11-17T08:31:43', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '251c5267-edd2-4e7d-805b-725457c64f65' | System | 17 Nov 2020 13:32:33 |
| User entered 'Yes (Y)' | System | 17 Nov 2020 13:32:33 |

US3222013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

Have you been exposed to someone with 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 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-11-17T08:31:49', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '251c5267-edd2-4e7d-805b-725457c64f65' | System | 17 Nov 2020 13:32:33 |
| User entered 'No (N)' | System | 17 Nov 2020 13:32:33 |

US3222013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-11-17T08:31:55', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '251c5267-edd2-4e7d-805b-725457c64f65' | System | 17 Nov 2020 13:32:33 |
| User entered 'No (N)' | System | 17 Nov 2020 13:32:33 |

US3222013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-11-17T08:32:04', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '251c5267-edd2-4e7d-805b-725457c64f65' | System | 17 Nov 2020 13:32:33 |
| User entered 'Yes (Y)' | System | 17 Nov 2020 13:32:33 |

US3222013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Please 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) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-11-17T08:32:13', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '251c5267-edd2-4e7d-805b-725457c64f65' | System | 17 Nov 2020 13:32:33 |
| User entered 'I confirm I have read this message and will call the study clinic immediately (9)' | System | 17 Nov 2020 13:32:33 |

US3222013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-11-17T08:32:21', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '251c5267-edd2-4e7d-805b-725457c64f65' | System | 17 Nov 2020 13:32:33 |
| User entered '17 Nov 2020 08:32:21' | System | 17 Nov 2020 13:32:33 |

US3222013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| Data entry locked. | System | 06 Aug 2020 18:45:15 |
| User entered '17 Nov 2020 00:01' | System | 06 Aug 2020 18:45:15 |

US3222013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:40:33 |
| Data entry locked. | System | 06 Aug 2020 18:45:15 |
| User entered '21 Nov 2020 23:59' | System | 06 Aug 2020 18:45:15 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered 'Day 110' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '21 Nov 2020 00:01' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '25 Nov 2020 23:59' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered 'Day 117' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-12-02T10:19:34', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '03538aa7-2ac5-4d6e-bed8-7b542274bfc6' | System | 02 Dec 2020 15:19:49 |
| User entered 'No (N)' | System | 02 Dec 2020 15:19:49 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-12-02T10:19:39', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '03538aa7-2ac5-4d6e-bed8-7b542274bfc6' | System | 02 Dec 2020 15:19:49 |
| User entered 'No (N)' | System | 02 Dec 2020 15:19:49 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-12-02T10:19:46', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '03538aa7-2ac5-4d6e-bed8-7b542274bfc6' User entered '02 Dec 2020 10:19:46' | System | 02 Dec 2020 15:19:49 |
| | System | 02 Dec 2020 15:19:49 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '28 Nov 2020 00:01' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '02 Dec 2020 23:59' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered 'Day 124' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-12-05T12:05:12', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '82576bcf-f562-4f02-b40c-8888eaa930c4' | System | 05 Dec 2020 17:05:31 |
| User entered 'No (N)' | System | 05 Dec 2020 17:05:31 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-12-05T12:05:17', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '82576bcf-f562-4f02-b40c-8888eaa930c4' | System | 05 Dec 2020 17:05:31 |
| User entered 'No (N)' | System | 05 Dec 2020 17:05:31 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2020-12-05T12:05:21', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '82576bcf-f562-4f02-b40c-8888eaa930c4' | System | 05 Dec 2020 17:05:31 |
| User entered '05 Dec 2020 12:05:21' | System | 05 Dec 2020 17:05:31 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '05 Dec 2020 00:01' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '09 Dec 2020 23:59' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered 'Day 131' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '12 Dec 2020 00:01' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '16 Dec 2020 23:59' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered 'Day 138' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '19 Dec 2020 00:01' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '23 Dec 2020 23:59' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered 'Day 145' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '26 Dec 2020 00:01' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '30 Dec 2020 23:59' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered 'Day 152' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2021-01-05T11:42:56', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '5f04e5cc-010e-4a35-8c77-7ebc182eb9d8' | System | 05 Jan 2021 16:43:14 |
| User entered 'No (N)' | System | 05 Jan 2021 16:43:14 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2021-01-05T11:43:01', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '5f04e5cc-010e-4a35-8c77-7ebc182eb9d8' | System | 05 Jan 2021 16:43:14 |
| User entered 'No (N)' | System | 05 Jan 2021 16:43:14 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2021-01-05T11:43:13', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '5f04e5cc-010e-4a35-8c77-7ebc182eb9d8' | System | 05 Jan 2021 16:43:14 |
| User entered '05 Jan 2021 11:43:13' | System | 05 Jan 2021 16:43:14 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '02 Jan 2021 00:01' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '06 Jan 2021 23:59' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered 'Day 159' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2021-01-09T10:39:31', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '81632610-ba02-452f-acb7-4be512555a5f' | System | 09 Jan 2021 15:39:42 |
| User entered 'No (N)' | System | 09 Jan 2021 15:39:42 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2021-01-09T10:39:35', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '81632610-ba02-452f-acb7-4be512555a5f' | System | 09 Jan 2021 15:39:42 |
| User entered 'No (N)' | System | 09 Jan 2021 15:39:42 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2021-01-09T10:39:41', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '81632610-ba02-452f-acb7-4be512555a5f' User entered '09 Jan 2021 10:39:41' | System | 09 Jan 2021 15:39:42 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '09 Jan 2021 00:01' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '13 Jan 2021 23:59' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered 'Day 166' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2021-01-16T10:17:15', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '0479833d-45f9-4c54-8d18-828665684670' | System | 16 Jan 2021 15:17:33 |
| User entered 'No (N)' | System | 16 Jan 2021 15:17:33 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2021-01-16T10:17:21', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '0479833d-45f9-4c54-8d18-828665684670' | System | 16 Jan 2021 15:17:33 |
| User entered 'No (N)' | System | 16 Jan 2021 15:17:33 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2021-01-16T10:17:33', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '0479833d-45f9-4c54-8d18-828665684670' User entered '16 Jan 2021 10:17:33' | System | 16 Jan 2021 15:17:33 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '16 Jan 2021 00:01' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '20 Jan 2021 23:59' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered 'Day 173' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2021-01-23T09:19:53', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '2bdefdb5-d3ec-484e-8f06-38c2bf57e6d9' | System | 23 Jan 2021 14:20:07 |
| User entered 'No (N)' | System | 23 Jan 2021 14:20:07 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2021-01-23T09:19:58', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '2bdefdb5-d3ec-484e-8f06-38c2bf57e6d9' | System | 23 Jan 2021 14:20:07 |
| User entered 'No (N)' | System | 23 Jan 2021 14:20:07 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2021-01-23T09:20:03', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '2bdefdb5-d3ec-484e-8f06-38c2bf57e6d9' | System | 23 Jan 2021 14:20:07 |
| User entered '23 Jan 2021 09:20:03' | System | 23 Jan 2021 14:20:07 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '23 Jan 2021 00:01' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '27 Jan 2021 23:59' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered 'Day 180' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '30 Jan 2021 00:01' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '03 Feb 2021 23:59' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered 'Day 187' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '06 Feb 2021 00:01' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '10 Feb 2021 23:59' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered 'Day 194' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2021-02-13T09:25:48', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '4faab7cc-af4d-4cac-b50d-9ba8f13f815d' | System | 13 Feb 2021 14:26:41 |
| User entered 'No (N)' | System | 13 Feb 2021 14:26:41 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2021-02-13T09:26:01', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '4faab7cc-af4d-4cac-b50d-9ba8f13f815d' | System | 13 Feb 2021 14:26:41 |
| User entered 'No (N)' | System | 13 Feb 2021 14:26:41 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2021-02-13T09:26:38', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '4faab7cc-af4d-4cac-b50d-9ba8f13f815d' | System | 13 Feb 2021 14:26:41 |
| User entered '13 Feb 2021 09:26:38' | System | 13 Feb 2021 14:26:41 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '13 Feb 2021 00:01' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '17 Feb 2021 23:59' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered 'Day 201' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2021-02-20T09:00:07', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'd86de06c-54ba-40bb-8248-e19c80b53d0c' | System | 20 Feb 2021 14:00:35 |
| User entered 'No (N)' | System | 20 Feb 2021 14:00:35 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2021-02-20T09:00:14', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'd86de06c-54ba-40bb-8248-e19c80b53d0c' | System | 20 Feb 2021 14:00:35 |
| User entered 'No (N)' | System | 20 Feb 2021 14:00:35 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2021-02-20T09:00:25', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'd86de06c-54ba-40bb-8248-e19c80b53d0c' | System | 20 Feb 2021 14:00:35 |
| User entered '20 Feb 2021 09:00:25' | System | 20 Feb 2021 14:00:35 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '20 Feb 2021 00:01' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '24 Feb 2021 23:59' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered 'Day 208' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2021-02-27T08:38:16-05:00', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '5679a794-bf13-4d50-a98e-03d0bd8af934' User entered 'No (N)' | System | 27 Feb 2021 13:38:29 |
| | System | 27 Feb 2021 13:38:29 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2021-02-27T08:38:20-05:00', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '5679a794-bf13-4d50-a98e-03d0bd8af934' | System | 27 Feb 2021 13:38:29 |
| User entered 'No (N)' | System | 27 Feb 2021 13:38:29 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2021-02-27T08:38:25-05:00', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '5679a794-bf13-4d50-a98e-03d0bd8af934' | System | 27 Feb 2021 13:38:29 |
| User entered '27 Feb 2021 08:38:25' | System | 27 Feb 2021 13:38:29 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '27 Feb 2021 00:01' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '03 Mar 2021 23:59' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered 'Day 215' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2021-03-06T12:56:58-05:00', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'b22c8905-51c1-4d02-9314-ad8d45caf973' | System | 06 Mar 2021 17:57:10 |
| User entered 'No (N)' | System | 06 Mar 2021 17:57:10 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2021-03-06T12:57:02-05:00', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'b22c8905-51c1-4d02-9314-ad8d45caf973' | System | 06 Mar 2021 17:57:10 |
| User entered 'No (N)' | System | 06 Mar 2021 17:57:10 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2021-03-06T12:57:08-05:00', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: 'b22c8905-51c1-4d02-9314-ad8d45caf973' | System | 06 Mar 2021 17:57:10 |
| User entered '06 Mar 2021 12:57:08' | System | 06 Mar 2021 17:57:10 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '06 Mar 2021 00:01' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '10 Mar 2021 23:59' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered 'Day 222' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2021-03-13T12:58:20-05:00', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '7f104999-688c-4817-a71f-6ea1bc098cf9' | System | 13 Mar 2021 17:58:31 |
| User entered 'No (N)' | System | 13 Mar 2021 17:58:31 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2021-03-13T12:58:24-05:00', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '7f104999-688c-4817-a71f-6ea1bc098cf9' | System | 13 Mar 2021 17:58:31 |
| User entered 'No (N)' | System | 13 Mar 2021 17:58:31 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2021-03-13T12:58:29-05:00', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '7f104999-688c-4817-a71f-6ea1bc098cf9' | System | 13 Mar 2021 17:58:31 |
| User entered '13 Mar 2021 12:58:29' | System | 13 Mar 2021 17:58:31 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '13 Mar 2021 00:01' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '17 Mar 2021 23:59' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered 'Day 229' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2021-03-20T13:32:08-04:00', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '3e6bd721-e7b6-41d7-9e50-4324ddae2e72' | System | 20 Mar 2021 17:32:34 |
| User entered 'No (N)' | System | 20 Mar 2021 17:32:34 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2021-03-20T13:32:16-04:00', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '3e6bd721-e7b6-41d7-9e50-4324ddae2e72' | System | 20 Mar 2021 17:32:34 |
| User entered 'No (N)' | System | 20 Mar 2021 17:32:34 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2021-03-20T13:32:26-04:00', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '3e6bd721-e7b6-41d7-9e50-4324ddae2e72' | System | 20 Mar 2021 17:32:34 |
| User entered '20 Mar 2021 13:32:26' | System | 20 Mar 2021 17:32:34 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '20 Mar 2021 00:01' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '24 Mar 2021 23:59' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered 'Day 236' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2021-03-27T10:41:37-04:00', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '82a62fd8-63e8-4259-b2bf-2fa99ecb1e80' | System | 27 Mar 2021 14:42:00 |
| User entered 'No (N)' | System | 27 Mar 2021 14:42:00 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2021-03-27T10:41:42-04:00', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '82a62fd8-63e8-4259-b2bf-2fa99ecb1e80' | System | 27 Mar 2021 14:42:00 |
| User entered 'No (N)' | System | 27 Mar 2021 14:42:00 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2021-03-27T10:41:55-04:00', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '82a62fd8-63e8-4259-b2bf-2fa99ecb1e80' | System | 27 Mar 2021 14:42:00 |
| User entered '27 Mar 2021 10:41:55' | System | 27 Mar 2021 14:42:00 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '27 Mar 2021 00:01' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '31 Mar 2021 23:59' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered 'Day 243' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2021-04-03T12:20:18-04:00', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '97a52d13-ce37-445f-98be-4c550b84d413' User entered 'No (N)' | System | 03 Apr 2021 16:20:47 |
| | System | 03 Apr 2021 16:20:47 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2021-04-03T12:20:21-04:00', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '97a52d13-ce37-445f-98be-4c550b84d413' | System | 03 Apr 2021 16:20:47 |
| User entered 'No (N)' | System | 03 Apr 2021 16:20:47 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2021-04-03T12:20:23-04:00', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '97a52d13-ce37-445f-98be-4c550b84d413' | System | 03 Apr 2021 16:20:47 |
| User entered '03 Apr 2021 12:20:23' | System | 03 Apr 2021 16:20:47 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '03 Apr 2021 00:01' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '07 Apr 2021 23:59' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered 'Day 250' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2021-04-10T08:14:22-04:00', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '8c29e926-3b05-4b52-a9af-0d1ce6432215' User entered 'No (N)' | System | 10 Apr 2021 12:14:35 |
| | System | 10 Apr 2021 12:14:35 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2021-04-10T08:14:24-04:00', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '8c29e926-3b05-4b52-a9af-0d1ce6432215' | System | 10 Apr 2021 12:14:35 |
| User entered 'No (N)' | System | 10 Apr 2021 12:14:35 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2021-04-10T08:14:27-04:00', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '8c29e926-3b05-4b52-a9af-0d1ce6432215' User entered '10 Apr 2021 08:14:27' | System | 10 Apr 2021 12:14:35 |
| | System | 10 Apr 2021 12:14:35 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '10 Apr 2021 00:01' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '14 Apr 2021 23:59' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered 'Day 257' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2021-04-17T17:37:34-04:00', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '83590eee-c3ba-46e9-8576-6ca890b93dbb' User entered 'No (N)' | System | 17 Apr 2021 21:37:55 |
| | System | 17 Apr 2021 21:37:55 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2021-04-17T17:37:43-04:00', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '83590eee-c3ba-46e9-8576-6ca890b93dbb' | System | 17 Apr 2021 21:37:55 |
| User entered 'No (N)' | System | 17 Apr 2021 21:37:55 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2021-04-17T17:37:49-04:00', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '83590eee-c3ba-46e9-8576-6ca890b93dbb' User entered '17 Apr 2021 17:37:49' | System | 17 Apr 2021 21:37:55 |
| | System | 17 Apr 2021 21:37:55 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '17 Apr 2021 00:01' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '21 Apr 2021 23:59' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered 'Day 264' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '24 Apr 2021 00:01' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '28 Apr 2021 23:59' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered 'Day 271' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2021-05-01T09:13:10-04:00', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '5f44fc02-0c83-427c-9c05-d942095c1b40' | System | 01 May 2021 13:13:25 |
| User entered 'No (N)' | System | 01 May 2021 13:13:25 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2021-05-01T09:13:15-04:00', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '5f44fc02-0c83-427c-9c05-d942095c1b40' | System | 01 May 2021 13:13:25 |
| User entered 'No (N)' | System | 01 May 2021 13:13:25 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2021-05-01T09:13:21-04:00', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '5f44fc02-0c83-427c-9c05-d942095c1b40' | System | 01 May 2021 13:13:25 |
| User entered '01 May 2021 09:13:21' | System | 01 May 2021 13:13:25 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '01 May 2021 00:01' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '05 May 2021 23:59' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered 'Day 278' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '08 May 2021 00:01' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '12 May 2021 23:59' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered 'Day 285' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '15 May 2021 00:01' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '19 May 2021 23:59' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered 'Day 292' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '22 May 2021 00:01' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '26 May 2021 23:59' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered 'Day 299' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '29 May 2021 00:01' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '02 Jun 2021 23:59' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered 'Day 306' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '05 Jun 2021 00:01' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '09 Jun 2021 23:59' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered 'Day 313' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '12 Jun 2021 00:01' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '16 Jun 2021 23:59' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered 'Day 320' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '19 Jun 2021 00:01' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '23 Jun 2021 23:59' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered 'Day 327' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '26 Jun 2021 00:01' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '30 Jun 2021 23:59' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered 'Day 334' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '03 Jul 2021 00:01' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '07 Jul 2021 23:59' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered 'Day 341' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '10 Jul 2021 00:01' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '14 Jul 2021 23:59' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered 'Day 348' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '17 Jul 2021 00:01' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '21 Jul 2021 23:59' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered 'Day 355' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '24 Jul 2021 00:01' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '28 Jul 2021 23:59' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered 'Day 362' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '31 Jul 2021 00:01' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '04 Aug 2021 23:59' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered 'Day 369' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '07 Aug 2021 00:01' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '11 Aug 2021 23:59' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered 'Day 376' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '14 Aug 2021 00:01' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '18 Aug 2021 23:59' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered 'Day 383' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '21 Aug 2021 00:01' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '25 Aug 2021 23:59' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered 'Day 390' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '28 Aug 2021 00:01' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '01 Sep 2021 23:59' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered 'Day 397' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '04 Sep 2021 00:01' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '08 Sep 2021 23:59' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered 'Day 404' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '11 Sep 2021 00:01' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '15 Sep 2021 23:59' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered 'Day 411' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '18 Sep 2021 00:01' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '22 Sep 2021 23:59' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered 'Day 418' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '25 Sep 2021 00:01' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '29 Sep 2021 23:59' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered 'Day 425' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '02 Oct 2021 00:01' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '06 Oct 2021 23:59' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered 'Day 432' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '09 Oct 2021 00:01' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '13 Oct 2021 23:59' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered 'Day 439' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '16 Oct 2021 00:01' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '20 Oct 2021 23:59' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered 'Day 446' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '23 Oct 2021 00:01' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '27 Oct 2021 23:59' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered 'Day 453' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '30 Oct 2021 00:01' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '03 Nov 2021 23:59' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered 'Day 460' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '06 Nov 2021 00:01' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '10 Nov 2021 23:59' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered 'Day 467' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '13 Nov 2021 00:01' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '17 Nov 2021 23:59' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered 'Day 474' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '20 Nov 2021 00:01' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '24 Nov 2021 23:59' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered 'Day 481' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '27 Nov 2021 00:01' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '01 Dec 2021 23:59' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered 'Day 488' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '04 Dec 2021 00:01' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '08 Dec 2021 23:59' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered 'Day 495' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '11 Dec 2021 00:01' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '15 Dec 2021 23:59' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered 'Day 502' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '18 Dec 2021 00:01' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '22 Dec 2021 23:59' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered 'Day 509' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '25 Dec 2021 00:01' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '29 Dec 2021 23:59' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered 'Day 516' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '01 Jan 2022 00:01' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '05 Jan 2022 23:59' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered 'Day 523' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '08 Jan 2022 00:01' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '12 Jan 2022 23:59' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered 'Day 530' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '15 Jan 2022 00:01' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '19 Jan 2022 23:59' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered 'Day 537' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '22 Jan 2022 00:01' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '26 Jan 2022 23:59' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered 'Day 544' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '29 Jan 2022 00:01' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '02 Feb 2022 23:59' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered 'Day 551' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '05 Feb 2022 00:01' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '09 Feb 2022 23:59' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered 'Day 558' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '12 Feb 2022 00:01' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '16 Feb 2022 23:59' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered 'Day 565' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '19 Feb 2022 00:01' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '23 Feb 2022 23:59' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered 'Day 572' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '26 Feb 2022 00:01' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '02 Mar 2022 23:59' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered 'Day 579' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '05 Mar 2022 00:01' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '09 Mar 2022 23:59' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered 'Day 586' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '12 Mar 2022 00:01' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '16 Mar 2022 23:59' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered 'Day 593' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '19 Mar 2022 00:01' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '23 Mar 2022 23:59' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered 'Day 600' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '26 Mar 2022 00:01' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '30 Mar 2022 23:59' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered 'Day 607' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '02 Apr 2022 00:01' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '06 Apr 2022 23:59' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered 'Day 614' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '09 Apr 2022 00:01' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '13 Apr 2022 23:59' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered 'Day 621' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '16 Apr 2022 00:01' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '20 Apr 2022 23:59' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered 'Day 628' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '23 Apr 2022 00:01' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '27 Apr 2022 23:59' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered 'Day 635' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '30 Apr 2022 00:01' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '04 May 2022 23:59' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered 'Day 642' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '07 May 2022 00:01' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '11 May 2022 23:59' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered 'Day 649' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '14 May 2022 00:01' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '18 May 2022 23:59' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered 'Day 656' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '21 May 2022 00:01' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '25 May 2022 23:59' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered 'Day 663' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '28 May 2022 00:01' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '01 Jun 2022 23:59' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered 'Day 670' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '04 Jun 2022 00:01' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '08 Jun 2022 23:59' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered 'Day 677' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '11 Jun 2022 00:01' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '15 Jun 2022 23:59' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered 'Day 684' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '18 Jun 2022 00:01' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '22 Jun 2022 23:59' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered 'Day 691' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '25 Jun 2022 00:01' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '29 Jun 2022 23:59' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered 'Day 698' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '02 Jul 2022 00:01' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '06 Jul 2022 23:59' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered 'Day 705' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '09 Jul 2022 00:01' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '13 Jul 2022 23:59' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered 'Day 712' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '16 Jul 2022 00:01' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '20 Jul 2022 23:59' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered 'Day 719' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '23 Jul 2022 00:01' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '27 Jul 2022 23:59' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered 'Day 726' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '30 Jul 2022 00:01' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '03 Aug 2022 23:59' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered 'Day 733' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '06 Aug 2022 00:01' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '10 Aug 2022 23:59' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered 'Day 740' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '13 Aug 2022 00:01' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '17 Aug 2022 23:59' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered 'Day 747' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '20 Aug 2022 00:01' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '24 Aug 2022 23:59' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered 'Day 754' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '27 Aug 2022 00:01' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '31 Aug 2022 23:59' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered 'Day 761' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '03 Sep 2022 00:01' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '07 Sep 2022 23:59' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered 'Day 768' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '10 Sep 2022 00:01' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '14 Sep 2022 23:59' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered 'Day 775' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '17 Sep 2022 00:01' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '21 Sep 2022 23:59' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered 'Day 782' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '24 Sep 2022 00:01' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '28 Sep 2022 23:59' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered 'Day 789' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '01 Oct 2022 00:01' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '05 Oct 2022 23:59' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered 'Day 796' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '08 Oct 2022 00:01' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:03:07

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 14:51:53 |
| Amendment Manager: User entered '12 Oct 2022 23:59' | System | 19 Nov 2020 14:51:53 |

US3222013

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:03:07

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 06:14:41 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2021-02-27T08:38:32-05:00', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '8f2c58ee-b019-4aee-8ef7-af8c5cc01077' | System | 27 Feb 2021 13:38:45 |
| User entered 'No (N)' | System | 27 Feb 2021 13:38:45 |

US3222013

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:03:07

[Date & Time of Submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 06:14:41 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (27b81bccf601f50e)', Time: '2021-02-27T08:38:38-05:00', User OID: 'PatientReportedOutcome (US3222013)', ODM File OID: '8f2c58ee-b019-4aee-8ef7-af8c5cc01077' | System | 27 Feb 2021 13:38:45 |
| User entered '27 Feb 2021 08:38:38' | System | 27 Feb 2021 13:38:45 |

US3222013

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:07

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'Yes (Y)' | (b) (4) Alicia Cevera (b) (4) | 07 Dec 2020 16:01:54 |

US3222013

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered '28 Oct 2020' | (b) (4) Alicia Cevera (b) (4) (b) (4) | 07 Dec 2020 16:01:54 |

US3222013

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:07

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'Contact Not Made (CONTACT NOT MADE)' | (b) (4) Alicia Cevera (b) (4) | 07 Dec 2020 16:01:54 |

US3222013

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:07

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered '3 ATTEMPTS MADE WITH NO RETURN CALLS' | Alicia Cevera (b) (4) | 07 Dec 2020 16:01:54 |

US3222013

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:07

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'Yes (Y)' | (b) (4) Alicia Cevera (b) (4) (b) (4) | 07 Dec 2020 16:01:58 |

US3222013

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:07

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 02:02:56 |
| User entered '1' | System | 07 Dec 2020 16:01:58 |

US3222013

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:07

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 10:26:03 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'Yes (Y)' | (b) (4) Alicia Cevera (b) (4) (b) (4) | 07 Dec 2020 16:02:28 |

US3222013

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 10:26:03 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered '30 Nov 2020' | Alicia Cevera (b) (4) | 07 Dec 2020 16:02:28 |

US3222013

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:07

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 10:26:03 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) Alicia Cevera (b) (4) (b) (4) | 07 Dec 2020 16:02:28 |

US3222013

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:07

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 10:26:03 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered empty. | (b) (4) Alicia Cevera (b) (4) (b) (4) | 07 Dec 2020 16:02:28 |

US3222013

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:07

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 10:26:03 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 01 Feb 2021 15:05:47 |

US3222013

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:07

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 10:26:03 |
| User entered 'I' | System | 01 Feb 2021 15:05:47 |

US3222013

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:07

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 10:26:03 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 01 Feb 2021 15:06:09 |

US3222013

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:07

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 10:26:03 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User closed query 'Data entered is non-conformant. Please correct.' (Site from System). | (b) (4) | 01 Feb 2021 15:06:15 |
| User entered '30 Dec 2020' reason for change: Data Entry Error | System | 01 Feb 2021 15:06:15 |
| User opened query 'Data entered is non-conformant. Please correct.' (Site from System). | (b) (4), (b) (6) | 01 Feb 2021 15:06:09 |
| User entered '30 Dec ' (non-conformant). | System | 01 Feb 2021 15:06:09 |
| | (b) (4), (b) (6) | 01 Feb 2021 15:06:09 |

US3222013

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:07

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 10:26:03 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) (b) (4), (b) (6) | 01 Feb 2021 15:06:09 |

US3222013

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:07

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 10:26:03 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 01 Feb 2021 15:06:09 |

US3222013

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:07

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 10:26:03 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 01 Feb 2021 15:06:19 |

US3222013

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:07

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 10:26:03 |
| User entered 'I' | System | 01 Feb 2021 15:06:19 |

US3222013

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:07

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 10:26:03 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 09 Feb 2021 12:56:43 |

US3222013

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 10:26:03 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered '01 Feb 2021' | (b) (4) (b) (4), (b) (6) | 09 Feb 2021 12:56:43 |

US3222013

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:07

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 10:26:03 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) (b) (4), (b) (6) | 09 Feb 2021 12:56:43 |

US3222013

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:07

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 10:26:03 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 09 Feb 2021 12:56:43 |

US3222013

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:07

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 10:26:03 |
| User signature succeeded. | Bruce Rankin (b) (4) | 25 Mar 2021 17:10:23 |
| User entered 'Yes (Y)' | (b) (4) douglas winter (b) (4) (b) (4) | 18 Mar 2021 21:29:57 |

US3222013

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:07

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 10:26:03 |
| User entered 'I' | System | 18 Mar 2021 21:29:57 |

US3222013

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:03:07

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 10:13:00 |
| User signature succeeded. | Bruce Rankin (b) (4) | 25 Mar 2021 17:10:23 |
| User entered 'Yes (Y)' | (b) (4) douglas winter (b) (4) | 18 Mar 2021 21:30:09 |

US3222013

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 10:13:00 |
| User signature succeeded. | Bruce Rankin (b) (4) | 25 Mar 2021 17:10:23 |
| User entered '16 Mar 2021' | (b) (4) douglas winter (b) (4) | 18 Mar 2021 21:30:09 |
| | (b) (4) | |

US3222013

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|--------------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 10:13:00 |
| User signature succeeded. | Bruce Rankin (b) (4) | 25 Mar 2021 17:10:23 |
| User entered 'Clinic (Clinic)' | (b) (4) douglas winter (b) (4) (b) (4) | 18 Mar 2021 21:30:09 |

US3222013

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:03:07

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 10:13:00 |
| User entered 'VISIT4' | System | 18 Mar 2021 21:30:09 |

US3222013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:07

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 10:13:00 |
| User signature succeeded. | Bruce Rankin (b) (4) | 05 Apr 2021 20:10:03 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 31 Mar 2021 13:23:02 |

US3222013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:07

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 10:13:00 |
| User signature succeeded. | Bruce Rankin (b) (4) | 05 Apr 2021 20:10:03 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 31 Mar 2021 13:23:02 |

US3222013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 10:13:00 |
| User signature succeeded. | Bruce Rankin (b) (4) | 05 Apr 2021 20:10:03 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 31 Mar 2021 13:23:02 |

US3222013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 10:13:00 |
| User entered empty. | System | 31 Mar 2021 13:23:02 |

US3222013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:07

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 10:13:00 |
| User signature succeeded. | Bruce Rankin (b) (4) | 05 Apr 2021 20:10:03 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 31 Mar 2021 13:23:02 |

US3222013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:07

[Route of measurement](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 10:13:00 |
| User signature succeeded. | Bruce Rankin (b) (4) | 05 Apr 2021 20:10:03 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 31 Mar 2021 13:23:02 |

US3222013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:07

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 10:13:00 |
| User signature succeeded. | Bruce Rankin (b) (4) | 05 Apr 2021 20:10:03 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 31 Mar 2021 13:23:02 |

US3222013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:07

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 10:13:00 |
| User signature succeeded. | Bruce Rankin (b) (4) | 05 Apr 2021 20:10:03 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 31 Mar 2021 13:23:02 |

US3222013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:07

[Pulse units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 10:13:00 |
| User entered empty. | System | 31 Mar 2021 13:23:02 |

US3222013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 10:13:00 |
| User signature succeeded. | Bruce Rankin (b) (4) | 05 Apr 2021 20:10:03 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 31 Mar 2021 13:23:02 |

US3222013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:07

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 10:13:00 |
| User entered empty. | System | 31 Mar 2021 13:23:02 |

US3222013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:07

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 10:13:00 |
| User signature succeeded. | Bruce Rankin (b) (4) | 05 Apr 2021 20:10:03 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 31 Mar 2021 13:23:02 |

US3222013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:07

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 10:13:00 |
| User entered empty. | System | 31 Mar 2021 13:23:02 |

US3222013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:07

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 10:13:00 |
| User signature succeeded. | Bruce Rankin (b) (4) | 05 Apr 2021 20:10:03 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 31 Mar 2021 13:23:02 |

US3222013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:07

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 10:13:00 |
| User entered empty. | System | 31 Mar 2021 13:23:02 |

US3222013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:07

Height (derived)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 10:13:00 |
| | | |

US3222013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:03:07

Weight (derived)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 10:13:00 |
| | | |

US3222013

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:03:07

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 10:13:00 |
| User signature succeeded. | Bruce Rankin (b) (4) | 25 Mar 2021 17:10:23 |
| User entered 'Yes (Y)' | (b) (4) douglas winter (b) (4) | 18 Mar 2021 21:30:17 |

US3222013

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:03:07

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 10:13:00 |
| User signature succeeded. | Bruce Rankin (b) (4) | 25 Mar 2021 17:10:23 |
| User entered '16 Mar 2021' | (b) (4) douglas winter (b) (4) (b) (4) | 18 Mar 2021 21:30:17 |

US3222013

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:03:07

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 10:13:00 |
| User signature succeeded. | Bruce Rankin (b) (4) | 25 Mar 2021 17:10:23 |
| User entered 'Yes (Y)' | (b) (4) douglas winter (b) (4) | 18 Mar 2021 21:30:31 |

US3222013

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:03:07

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 10:13:00 |
| User signature succeeded. | Bruce Rankin (b) (4) | 25 Mar 2021 17:10:23 |
| User entered '16 Mar 2021' | (b) (4) douglas winter (b) (4) | 18 Mar 2021 21:30:31 |
| | (b) (4) | |

US3222013

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:03:07

Collection time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 10:13:00 |
| User signature succeeded. | Bruce Rankin (b) (4) | 25 Mar 2021 17:10:23 |
| User entered '14:02' | (b) (4) douglas winter (b) (4) (b) (4) | 18 Mar 2021 21:30:31 |

US3222013

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 10:13:00 |
| User entered '16 Mar 2021 14:02' | System | 18 Mar 2021 21:30:31 |

US3222013

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:07

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 10:13:00 |
| User signature succeeded. | Bruce Rankin (b) (4) | 25 Mar 2021 17:10:23 |
| User entered 'Yes (Y)' | (b) (4) douglas winter (b) (4) | 18 Mar 2021 21:30:35 |

US3222013

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:07

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 10:13:00 |
| User entered 'I' | System | 18 Mar 2021 21:30:35 |

US3222013

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:07

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:45:28 |
| User signature succeeded. | Bruce Rankin (b) (4) | 05 Apr 2021 20:10:03 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 30 Mar 2021 14:06:18 |

US3222013

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:45:28 |
| User signature succeeded. | Bruce Rankin (b) (4) | 05 Apr 2021 20:10:03 |
| User entered '30 Mar 2021' | (b) (4) (b) (4), (b) (6) | 30 Mar 2021 14:06:18 |

US3222013

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:07

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:45:28 |
| User signature succeeded. | Bruce Rankin (b) (4) | 05 Apr 2021 20:10:03 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) (b) (4), (b) (6) | 30 Mar 2021 14:06:18 |

US3222013

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:07

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:45:28 |
| User signature succeeded. | Bruce Rankin (b) (4) | 05 Apr 2021 20:10:03 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 30 Mar 2021 14:06:18 |

US3222013

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:07

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:45:28 |
| User signature succeeded. | Bruce Rankin (b) (4) | 05 Apr 2021 20:10:03 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 30 Mar 2021 14:06:30 |

US3222013

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:07

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 04:45:28 |
| User entered 'I' | System | 30 Mar 2021 14:06:30 |

US3222013

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:07

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 03 May 2021 15:52:48 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 30 Apr 2021 13:24:52 |

US3222013

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 03 May 2021 15:52:48 |
| User entered '30 Apr 2021' | (b) (4) (b) (4), (b) (6) | 30 Apr 2021 13:24:52 |

US3222013

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:07

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 03 May 2021 15:52:48 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) (b) (4), (b) (6) | 30 Apr 2021 13:24:52 |

US3222013

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:03:07

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 03 May 2021 15:52:48 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 30 Apr 2021 13:24:52 |

US3222013

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:07

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 03 May 2021 15:52:48 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 30 Apr 2021 13:24:59 |

US3222013

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:03:07

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 30 Apr 2021 13:24:59 |

US3222013

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

Form: Visit Date

Generated On: 09 Jun 2021 16:03:07

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 08:58:05 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'Yes (Y)' | Diana Toney (b) (4) | 18 Jan 2021 20:00:22 |

US3222013

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

Form: Visit Date

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 08:58:05 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered '18 Jan 2021' | Diana Toney (b) (4) | 18 Jan 2021 20:00:22 |

US3222013

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

Form: Visit Date

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|--------------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 08:58:05 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'Clinic (Clinic)' | Diana Toney (b) (4) | 18 Jan 2021 20:00:22 |

US3222013

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

Form: Visit Date

Generated On: 09 Jun 2021 16:03:07

[Folder OID](#)

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 08:58:05 |
| User entered 'UNBLND_DECIDE' | System | 18 Jan 2021 20:00:22 |

US3222013

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

Form: Unblinding

Generated On: 09 Jun 2021 16:03:07

Date of updated informed consent (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 08:58:05 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered '18 Jan 2021' | (b) (4) Diana Toney (b) (4) (b) (4) | 18 Jan 2021 20:00:42 |

US3222013

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

Form: Unblinding

Generated On: 09 Jun 2021 16:03:07

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 08:58:05 |
| User signature succeeded. | Bruce Rankin (b) (4) | 25 Mar 2021 17:10:23 |
| User entered '0' | (b) (4) douglas winter (b) (4) | 18 Mar 2021 21:30:47 |
| Amendment Manager inserted this DataPoint. | (b) (4) System | 06 Mar 2021 03:10:21 |

US3222013

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

Form: Unblinding

Generated On: 09 Jun 2021 16:03:07

[Was the participant unblinded?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 08:58:05 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'Yes (Y)' | (b) (4) Diana Toney (b) (4) (b) (4) | 18 Jan 2021 20:00:42 |

US3222013

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

Form: Unblinding

Generated On: 09 Jun 2021 16:03:07

[Under what version of the Protocol was the Participant unblinded?](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 08:58:05 |
| User signature succeeded. | Bruce Rankin (b) (4) | 25 Mar 2021 17:10:23 |
| User entered 'Amendment 6 or later (Amendment 6 or later)' | (b) (4) | |
| | douglas winter (b) (4) | 18 Mar 2021 21:30:47 |
| | (b) (4) | |
| Amendment Manager inserted this DataPoint. | System | 06 Mar 2021 03:10:21 |

US3222013

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

Form: Unblinding

Generated On: 09 Jun 2021 16:03:07

Date of unblinding (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 08:58:05 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered '18 Jan 2021' | Diana Toney (b) (4) | 18 Jan 2021 20:00:42 |

US3222013

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

Form: Unblinding

Generated On: 09 Jun 2021 16:03:07

[Participant randomization assignment](#)

| Audit | User | Time (GMT) |
|--------------------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 08:58:05 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'mRNA-1273 (mRNA-1273)' | Diana Toney (b) (4) | 18 Jan 2021 20:00:42 |

US3222013

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

Form: Unblinding

Generated On: 09 Jun 2021 16:03:07

[Actual Dose 1](#)

| Audit | User | Time (GMT) |
|---|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 08:58:05 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)' | (b) (4) System | 20 Jan 2021 01:20:48 |
| User entered 'mRNA-1273 (mRNA-1273)' | Diana Toney (b) (4) (b) (4) | 18 Jan 2021 20:00:42 |

US3222013

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

Form: Unblinding

Generated On: 09 Jun 2021 16:03:07

[Actual Dose 2](#)

| Audit | User | Time (GMT) |
|---|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 08:58:05 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)' | (b) (4) System | 20 Jan 2021 01:20:48 |
| User entered 'mRNA-1273 (mRNA-1273)' | Diana Toney (b) (4) (b) (4) | 18 Jan 2021 20:00:42 |

US3222013

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

Form: Unblinding

Generated On: 09 Jun 2021 16:03:07

[Will participant receive mRNA-1273?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 08:58:05 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'No (N)' | (b) (4) Diana Toney (b) (4) (b) (4) | 18 Jan 2021 20:00:42 |

US3222013

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

Form: Unblinding

Generated On: 09 Jun 2021 16:03:07

[Placebo Only Flag](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 08:58:05 |
| User entered empty. | System | 18 Jan 2021 20:00:42 |

US3222013

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

Form: Unblinding

Generated On: 09 Jun 2021 16:03:07

[Continuing with mRNA-1273](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 08:58:05 |
| User entered empty. | System | 18 Jan 2021 20:00:42 |

US3222013

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:03:07

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 08:58:05 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'Yes (Y)' | Diana Toney (b) (4) | 18 Jan 2021 20:01:05 |

US3222013

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:03:07

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 08:58:05 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered '18 Jan 2021' | Diana Toney (b) (4) | 18 Jan 2021 20:01:05 |

US3222013

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:03:07

Collection time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 08:58:05 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered '14:00' | Diana Toney (b) (4) | 18 Jan 2021 20:01:05 |

US3222013

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:03:07

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 08:58:05 |
| User entered '18 Jan 2021 14:00' | System | 18 Jan 2021 20:01:05 |

US3222013

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:03:07

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 08:58:05 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'Yes (Y)' | Diana Toney (b) (4) | 18 Jan 2021 20:01:18 |

US3222013

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:03:07

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 08:58:05 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered '18 Jan 2021' | (b) (4) Diana Toney (b) (4) (b) (4) | 18 Jan 2021 20:01:18 |

US3222013

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:03:07

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 08:58:05 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered '14:05' | Diana Toney (b) (4) | 18 Jan 2021 20:01:18 |

US3222013

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:03:07

[Collection Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 08:58:05 |
| User entered '18 Jan 2021 14:05' | System | 18 Jan 2021 20:01:18 |

US3222013

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 16:03:07

[Did the participant experience any adverse events?](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 15:31:40 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | (b) (4) | |
| | douglas winter (b) (4) | 17 Nov 2020 18:39:55 |
| User entered 'No (N)' | (b) (4) | |
| | Amber Vasquez (b) (4) | 06 Aug 2020 19:31:14 |
| | (b) (4) | |

US3222013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:07

[AEID](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 18 Nov 2020 20:37:54 |
| User entered 'USA-US104-2020-mRNA-1273-P301000018' | System | 18 Nov 2020 20:37:49 |
| User entered 'New' | (b) (4), (b) (6) | 18 Nov 2020 20:37:49 |

US3222013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:07

[Adverse event](#)

| Audit | User | Time (GMT) |
|---|----------------------------------|----------------------|
| User closed query 'Per CDM: Per previous query response "Updated"; however, please provide location of update such as log line number. Thank you.' (Site from DM). | (b) (4), (b) (6) | 28 Dec 2020 20:39:28 |
| Query 'Per CDM: Per previous query response "Updated"; however, please provide location of update such as log line number. Thank you.' answered with 'PREVIOUS QUERY REQUESTED THAT AE TERM BE UPDATED, THIS IS WHAT WAS UPDATED. IF THERE ARE OTHERS TO BE UPDATED, PLEASE BE VERY CLEAR.' (Site from DM). | Albert Garcia (b) (4) (b) (4) | 18 Dec 2020 16:51:40 |
| User opened query 'Per CDM: Per previous query response "Updated"; however, please provide location of update such as log line number. Thank you.' (Site from DM). | (b) (4), (b) (6) | 17 Dec 2020 08:56:23 |
| User closed query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of ATRIAL FIBRILLATION. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify.' (Site from DM). | (b) (4), (b) (6) | 17 Dec 2020 08:55:56 |
| User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial fibrillation, LLT: Atrial fibrillation aggravated - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 11 Dec 2020 18:35:51 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 11 Dec 2020 18:35:51 |
| Data point term sent to Coder | System | 11 Dec 2020 13:15:12 |
| Query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of ATRIAL FIBRILLATION. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify.' answered with 'UPDATED' (Site from DM). | Albert Garcia (b) (4) (b) (4) | 11 Dec 2020 13:15:09 |
| Coding entries removed. | Albert Garcia (b) (4) (b) (4) | 11 Dec 2020 13:14:45 |
| User entered 'ATRIAL FIBRILLATION - WORSENING' reason for change: Data Entry Error | Albert Garcia (b) (4) (b) (4) | 11 Dec 2020 13:14:45 |

US3222013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:07

[Adverse event](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| User opened query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of ATRIAL FIBRILLATION. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify.' (Site from DM). | (b) (4), (b) (6) | 08 Dec 2020 02:07:23 |
| User coded data point as SOC: Cardiac disorders, HLT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial fibrillation, LLT: Atrial fibrillation - version MedDRA\\23.0. | Coder Import (b) (4) | 17 Nov 2020 18:45:51 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | (b) (4) | 17 Nov 2020 18:45:51 |
| Data point term sent to Coder | System | 17 Nov 2020 18:45:08 |
| User entered 'ATRIAL FIBRILLATION' | douglas winter (b) (4) | 17 Nov 2020 18:44:10 |
| | (b) (4) | |

US3222013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:07

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | douglas winter (b) (4) (b) (4) | 17 Nov 2020 18:44:10 |

US3222013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:07

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|-----------------------|-----------------------------------|----------------------|
| User entered 'No (N)' | douglas winter (b) (4) (b) (4) | 17 Nov 2020 18:44:10 |

US3222013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:07

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| User closed query 'Data is required. Please complete.' (Site from System). | System | 17 Nov 2020 18:45:25 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 17 Nov 2020 18:45:25 |
| User entered 'No (N)' reason for change: Data Entry Error | douglas winter (b) (4) (b) (4) | 17 Nov 2020 18:45:25 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 17 Nov 2020 18:44:10 |
| User entered empty. | douglas winter (b) (4) (b) (4) | 17 Nov 2020 18:44:10 |

US3222013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:07

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------------|----------------------|
| User entered '14 Nov 2020' | douglas winter (b) (4) (b) (4) | 17 Nov 2020 18:44:10 |

US3222013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:07

Start time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | douglas winter (b) (4) (b) (4) | 17 Nov 2020 18:44:10 |

US3222013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:07

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 17 Nov 2020 18:44:10 |

US3222013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:07

[Ongoing?](#)

| Audit | User | Time (GMT) |
|-----------------------|-----------------------------------|----------------------|
| User entered 'No (N)' | douglas winter (b) (4) (b) (4) | 17 Nov 2020 18:44:10 |

US3222013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:07

If not Ongoing, end date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------------|----------------------|
| User entered '16 Nov 2020' | douglas winter (b) (4) (b) (4) | 17 Nov 2020 18:44:10 |

US3222013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:07

End time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | douglas winter (b) (4) (b) (4) | 17 Nov 2020 18:44:10 |

US3222013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:07

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 17 Nov 2020 18:44:10 |

US3222013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:07

[Severity](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| User entered 'Grade 4 (Grade 4)' reason for change: | Albert Garcia (b) (4) | 02 Dec 2020 14:12:02 |
| Data Entry Error | (b) (4) | |
| User entered 'Grade 3/Severe (Grade 3/Severe)' | douglas winter (b) (4) | 17 Nov 2020 18:44:10 |
| | (b) (4) | |

US3222013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:07

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| 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 | 17 Nov 2020 18:45:25 |
| 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 | 17 Nov 2020 18:44:10 |
| User entered 'Yes (Y)' | douglas winter (b) (4) (b) (4) | 17 Nov 2020 18:44:10 |

US3222013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:07

[Death](#)

| Audit | User | Time (GMT) |
|------------------|-----------------------------------|----------------------|
| User entered '0' | douglas winter (b) (4) (b) (4) | 17 Nov 2020 18:44:10 |

US3222013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:07

[Life threatening](#)

| Audit | User | Time (GMT) |
|------------------|-----------------------------------|----------------------|
| User entered '0' | douglas winter (b) (4) (b) (4) | 17 Nov 2020 18:44:10 |

US3222013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:07

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System). | System | 17 Nov 2020 18:45:25 |
| 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). | | 17 Nov 2020 18:45:25 |
| User entered '1' reason for change: Data Entry Error douglas winter | (b) (4) | 17 Nov 2020 18:45:25 |
| | (b) (4) | |
| 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 | 17 Nov 2020 18:44:10 |
| User entered '0' | douglas winter (b) (4) | 17 Nov 2020 18:44:10 |
| | (b) (4) | |

US3222013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:07

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------------|----------------------|
| User entered '14 Nov 2020' | douglas winter (b) (4) (b) (4) | 17 Nov 2020 18:44:10 |

US3222013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:07

Hospital Discharge Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------------|----------------------|
| User entered '16 Nov 2020' | douglas winter (b) (4) (b) (4) | 17 Nov 2020 18:44:10 |

US3222013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:07

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|-----------------------|-----------------------------------|----------------------|
| User entered 'No (N)' | douglas winter (b) (4) (b) (4) | 17 Nov 2020 18:44:10 |

US3222013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:07

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | douglas winter (b) (4) (b) (4) | 17 Nov 2020 18:44:10 |

US3222013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:07

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|------------------|-----------------------------------|----------------------|
| User entered '0' | douglas winter (b) (4) (b) (4) | 17 Nov 2020 18:44:10 |

US3222013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:07

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|------------------|-----------------------------------|----------------------|
| User entered '0' | douglas winter (b) (4) (b) (4) | 17 Nov 2020 18:44:10 |

US3222013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:07

[Other medically important event](#)

| Audit | User | Time (GMT) |
|------------------|-----------------------------------|----------------------|
| User entered '0' | douglas winter (b) (4) (b) (4) | 17 Nov 2020 18:44:10 |

US3222013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:07

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| User entered 'Not Related (NOT RELATED)' | douglas winter (b) (4) (b) (4) | 17 Nov 2020 18:44:10 |

US3222013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:07

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| User entered 'Not Related (NOT RELATED)' | douglas winter (b) (4) (b) (4) | 17 Nov 2020 18:44:10 |

US3222013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:07

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| User entered 'Not Applicable (NOT APPLICABLE)' | douglas winter (b) (4) (b) (4) | 17 Nov 2020 18:44:10 |

US3222013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:07

None

| Audit | User | Time (GMT) |
|------------------|-----------------------------------|----------------------|
| User entered '0' | douglas winter (b) (4) (b) (4) | 17 Nov 2020 18:44:10 |

US3222013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:07

Concomitant Medication

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| User closed query 'Per DM RQ: Other Action Taken = Concomitant Medication. However, ConMed recorded was given prior to the start date of this worsening condition and appears to be used for the MH of Atrial Fibrillation. Please review and confirm if there are new medications used to treat this worsening condition. If yes, review and add a Con Medication as appropriate or update action taken. ' (Site from DM). | (b) (4), (b) (6) | 28 Dec 2020 20:39:49 |
| Query 'Per DM RQ: Other Action Taken = Concomitant Medication. However, ConMed recorded was given prior to the start date of this worsening condition and appears to be used for the MH of Atrial Fibrillation. Please review and confirm if there are new medications used to treat this worsening condition. If yes, review and add a Con Medication as appropriate or update action taken. ' answered with 'THERE WAS NO NEW MEDICATIONS. ' (Site from DM). | Albert Garcia (b) (4) (b) (4) | 18 Dec 2020 16:52:16 |
| User opened query 'Per DM RQ: Other Action Taken = Concomitant Medication. However, ConMed recorded was given prior to the start date of this worsening condition and appears to be used for the MH of Atrial Fibrillation. Please review and confirm if there are new medications used to treat this worsening condition. If yes, review and add a Con Medication as appropriate or update action taken. ' (Site from DM). | (b) (4), (b) (6) | 17 Dec 2020 08:57:54 |
| User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, ConMed recorded was given prior to the start date of this worsening condition and appears to be used for the MH of Atrial Fibrillation. Please review and confirm if there are new medications used to treat this worsening condition. If yes, review and add a Con Medication as appropriate or update action taken. ' (Site from DM). | (b) (4), (b) (6) | 17 Dec 2020 08:57:30 |

US3222013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:07

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, ConMed recorded was given prior to the start date of this worsening condition and appears to be used for the MH of Atrial Fibrillation. Please review and confirm if there are new medications used to treat this worsening condition. If yes, review and add a Con Medication as appropriate or update action taken.' answered with 'NO NEW CONMEDS LISTED.' (Site from DM). | Albert Garcia (b) (4) (b) (4) | 11 Dec 2020 13:16:06 |
| User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, ConMed recorded was given prior to the start date of this worsening condition and appears to be used for the MH of Atrial Fibrillation. Please review and confirm if there are new medications used to treat this worsening condition. If yes, review and add a Con Medication as appropriate or update action taken.' (Site from DM). | (b) (4), (b) (6) (b) (4) | 08 Dec 2020 02:07:43 |
| User entered 'I' | douglas winter (b) (4) (b) (4) | 17 Nov 2020 18:44:10 |

US3222013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:07

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|------------------|-----------------------------------|----------------------|
| User entered '0' | douglas winter (b) (4) (b) (4) | 17 Nov 2020 18:44:10 |

US3222013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:07

[Outcome](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | douglas winter (b) (4) (b) (4) | 17 Nov 2020 18:44:10 |

US3222013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:07

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit | User | Time (GMT) |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | douglas winter (b) (4) (b) (4) | 17 Nov 2020 18:44:10 |

US3222013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:07

[Narrative](#)

| Audit | User | Time (GMT) |
|---|----------------------------------|----------------------|
| 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. Please leave query open until information is available.' (Site from Safety). | (b) (4), (b) (6) | 09 Apr 2021 18:06:46 |
| User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. Please leave query open until information is available.' (Site from Safety). | (b) (4), (b) (6) | 09 Apr 2021 18:06:13 |
| User closed 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) | 09 Apr 2021 16:24:59 |
| User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety). | (b) (4), (b) (6) | 09 Apr 2021 16:24:55 |
| 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.' answered with 'AS NOTED IN THE RESPONSE, RECORDS HAVE BEEN REQUESTED SO INFORMATION CAN BE UPDATED. ONCE RECEIVED, ALL DATA WILL BE ADDED TO EDC. ' (Site from Safety). | Albert Garcia (b) (4) (b) (4) | 08 Apr 2021 13:20:30 |

US3222013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:07

[Narrative](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'AS NOTED IN THE RESPONSE, RECORDS HAVE BEEN REQUESTED SO INFORMATION CAN BE UPDATED. ONCE RECEIVED, ALL DATA WILL BE ADDED TO EDC. ' (Site from Safety). | Albert Garcia (b) (4) (b) (4) | 08 Apr 2021 13:20:07 |
| 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) (b) (4) | 08 Dec 2020 22:21:37 |
| User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety). | (b) (4), (b) (6) (b) (4) | 08 Dec 2020 22:21:21 |
| User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. ' (Site from Safety). | (b) (4), (b) (6) (b) (4) | 03 Dec 2020 16:52:08 |
| User closed 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) (b) (4) | 03 Dec 2020 16:52:03 |
| User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety). | (b) (4), (b) (6) (b) (4) | 03 Dec 2020 16:52:00 |
| User closed query 'PV Query: As the subject was admitted to the hospital please consider updating the severity of the event to Grade 4. ' (Site from Safety). | (b) (4), (b) (6) (b) (4) | 03 Dec 2020 16:51:55 |

US3222013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:07

[Narrative](#)

| Audit | User | Time (GMT) |
|--|--------------------------------------|----------------------|
| Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. ' answered with 'DISCHARGE SUMMARY HAS NOT BEEN RECEIVED' (Site from Safety). | Albert Garcia (b) (4) (b) (4) | 02 Dec 2020 14:11:39 |
| 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. ' answered with 'DISCHARGE SUMMARY HAS NOT BEEN RECEIVED' (Site from Safety). | Albert Garcia (b) (4) (b) (4) | 02 Dec 2020 14:11:33 |
| Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'DISCHARGE SUMMARY HAS NOT YET BEEN RECEIVED. ' (Site from Safety). | Albert Garcia (b) (4) (b) (4) | 02 Dec 2020 14:10:35 |
| Query 'PV Query: As the subject was admitted to the hospital please consider updating the severity of the event to Grade 4. ' answered with 'AE PAGE HAS BEEN UPDATED. ' (Site from Safety). | Albert Garcia (b) (4) (b) (4) | 02 Dec 2020 13:54:25 |
| Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. ' canceled (Site from Safety). | (b) (4), (b) (6) (b) (4), (b) (6) | 25 Nov 2020 21:24:47 |
| 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) (b) (4), (b) (6) | 25 Nov 2020 20:08:56 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:07

[Narrative](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| 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) | 25 Nov 2020 20:08:43 |
| User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety). | (b) (4), (b) (6) | 25 Nov 2020 20:08:29 |
| User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. ' (Site from Safety). | (b) (4), (b) (6) | 25 Nov 2020 20:08:18 |
| User opened query 'PV Query: As the subject was admitted to the hospital please consider updating the severity of the event to Grade 4. ' (Site from Safety). | (b) (4), (b) (6) | 25 Nov 2020 20:07:49 |
| User entered 'I WAS INFORMED OF THE SAE AT 11 AM ON 17/NOV/2020. I SPOKE WITH THE WIFE TODAY AND SHE SAID HE NORMALLY GOES TO THE HOSPITAL ONCE OR TWICE A YEAR FOR A-FIB ISSUES. HE HAS FULLY RECOVERED. I REQUESTED MEDICAL RECORDS.' | douglas winter (b) (4) (b) (4) | 17 Nov 2020 18:44:10 |

US3222013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:07

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 17 Nov 2020 18:44:10 |

US3222013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:07

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 17 Nov 2020 18:44:10 |

US3222013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:03:07

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '0' | System | 17 Nov 2020 18:44:10 |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 16:03:07

[Were any prior/concomitant medications and/or vaccinations taken?](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 15:31:40 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | (b) (4) Thais Truffa (b) (4) | 18 Sep 2020 15:38:27 |
| User entered 'No (N)' | Amber Vasquez (b) (4) (b) (4) | 06 Aug 2020 19:31:34 |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:03:07

Name of Medication

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTI-DEMENTIA DRUGS, ATC: ANTICHOLINESTERASES, PRODUCT: DONEPEZIL - version WHODrug-Global-B3\\202003. | (b) (4) Coder Import (b) (4) | 18 Sep 2020 21:55:40 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 18 Sep 2020 21:55:40 |
| Data point term sent to Coder | System | 18 Sep 2020 16:01:55 |
| User entered 'Donepezil' | Thais Truffa (b) (4) (b) (4) | 18 Sep 2020 16:01:10 |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:03:07

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| User entered 'No (N)' | Thais Truffa (b) (4) | 18 Sep 2020 16:01:10 |
| | | |
| | | |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:03:07

[Indication](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 14:24:39 |
| Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'PT COULD NOT PROVIDE AN OFFICIAL MEDICAL DIAGNOSIS. THEREFORE, MEMORY LOSS IS THE BEST ENTRY OPTION AT THIS POINT. ' (Site from DM). | Albert Garcia (b) (4) (b) (4) | 31 Oct 2020 13:14:07 |
| User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM). | (b) (4), (b) (6) | 29 Oct 2020 21:00:59 |
| User entered 'Memory loss' | Thais Truffa (b) (4) | 18 Sep 2020 16:01:10 |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:03:07

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| User entered '10' | Thais Truffa (b) (4) | 18 Sep 2020 16:01:10 |
| | | |
| | | |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:03:07

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| User entered 'mg (mg)' | Thais Truffa (b) (4) | 18 Sep 2020 16:01:10 |
| | | |
| | | |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:03:07

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| User entered empty. | Thais Truffa (b) (4) | 18 Sep 2020 16:01:10 |
| | | |
| | | |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:03:07

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| User entered 'once daily (QD)' | Thais Truffa (b) (4) | 18 Sep 2020 16:01:10 |
| | | |
| | | |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:03:07

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| User entered empty. | Thais Truffa (b) (4) | 18 Sep 2020 16:01:10 |
| | | |
| | | |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:03:07

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| User entered 'Oral (ORAL)' | Thais Truffa (b) (4) | 18 Sep 2020 16:01:10 |
| | | |
| | | |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:03:07

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| User entered empty. | Thais Truffa (b) (4) | 18 Sep 2020 16:01:10 |
| | | |
| | | |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:03:07

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| User entered 'UN UNK 2020' | Thais Truffa (b) (4) | 18 Sep 2020 16:01:10 |
| | | |
| | | |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:03:07

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| User entered '0' | Thais Truffa (b) (4) | 18 Sep 2020 16:01:10 |
| | | |
| | | |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:03:07

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Thais Truffa (b) (4) | 18 Sep 2020 16:01:10 |
| | | |
| | | |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:03:07

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| User entered empty. | Thais Truffa (b) (4) | 18 Sep 2020 16:01:10 |
| | | |
| | | |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:03:07

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| User entered 'No (N)' | Thais Truffa (b) (4) | 18 Sep 2020 16:01:10 |
| | | |
| | | |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:03:07

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 18 Sep 2020 16:01:10 |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:03:07

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 18 Sep 2020 16:01:10 |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:03:07

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 18 Sep 2020 16:01:10 |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:03:07

Name of Medication

| Audit | User | Time (GMT) |
|---|--|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: FIBRATES, PRODUCT: FENOFIBRATE - version WHODrug-Global-B3\\202003. | (b) (4) Coder Import (b) (4) (b) (4) | 18 Sep 2020 16:07:09 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 18 Sep 2020 16:07:09 |
| Data point term sent to Coder | System | 18 Sep 2020 16:06:08 |
| User entered 'Fenofibrate' | Thais Truffa (b) (4) (b) (4) (b) (4) | 18 Sep 2020 16:05:59 |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:03:07

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| User entered 'No (N)' | Thais Truffa (b) (4) | 18 Sep 2020 16:05:59 |
| | | |
| | | |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:03:07

[Indication](#)

| Audit | User | Time (GMT) |
|-------------------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| User entered 'Hypercholesterolemia' | Thais Truffa (b) (4) | 18 Sep 2020 16:05:59 |
| | | |
| | | |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:03:07

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| User entered '54' | Thais Truffa (b) (4) | 18 Sep 2020 16:05:59 |
| | | |
| | | |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:03:07

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| User entered 'mg (mg)' | Thais Truffa (b) (4) | 18 Sep 2020 16:05:59 |
| | | |
| | | |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:03:07

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| User entered empty. | Thais Truffa (b) (4) | 18 Sep 2020 16:05:59 |
| | | |
| | | |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:03:07

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|---------------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'once daily (QD)' | (b) (4) Thais Truffa (b) (4) | 18 Sep 2020 16:05:59 |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:03:07

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| User entered empty. | Thais Truffa (b) (4) | 18 Sep 2020 16:05:59 |
| | | |
| | | |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:03:07

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| User entered 'Oral (ORAL)' | Thais Truffa (b) (4) | 18 Sep 2020 16:05:59 |
| | | |
| | | |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:03:07

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| User entered empty. | Thais Truffa (b) (4) | 18 Sep 2020 16:05:59 |
| | | |
| | | |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:03:07

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| User entered 'UN UNK 2020' | Thais Truffa (b) (4) | 18 Sep 2020 16:05:59 |
| | | |
| | | |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:03:07

Start date completely unknown

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| User entered '0' | Thais Truffa (b) (4) | 18 Sep 2020 16:05:59 |
| | | |
| | | |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:03:07

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Thais Truffa (b) (4) | 18 Sep 2020 16:05:59 |
| | | |
| | | |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:03:07

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| User entered empty. | Thais Truffa (b) (4) | 18 Sep 2020 16:05:59 |
| | | |
| | | |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:03:07

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| User entered 'No (N)' | Thais Truffa (b) (4) | 18 Sep 2020 16:05:59 |
| | | |
| | | |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:03:07

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 18 Sep 2020 16:05:59 |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:03:07

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 18 Sep 2020 16:05:59 |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:03:07

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 18 Sep 2020 16:05:59 |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:03:07

Name of Medication

| Audit | User | Time (GMT) |
|--|--|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: LOVASTATIN - version WHODrug-Global-B3\\202003. | (b) (4) Coder Import (b) (4) (b) (4) | 18 Sep 2020 16:14:46 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 18 Sep 2020 16:14:46 |
| Data point term sent to Coder | System | 18 Sep 2020 16:13:27 |
| User entered 'Lovastatin' | Thais Truffa (b) (4) (b) (4) (b) (4) | 18 Sep 2020 16:12:49 |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:03:07

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| User entered 'No (N)' | Thais Truffa (b) (4) | 18 Sep 2020 16:12:49 |
| | | |
| | | |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:03:07

[Indication](#)

| Audit | User | Time (GMT) |
|-------------------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| User entered 'Hypercholesterolemia' | Thais Truffa (b) (4) | 18 Sep 2020 16:12:49 |
| | | |
| | | |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:03:07

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| User entered '40' | Thais Truffa (b) (4) | 18 Sep 2020 16:12:49 |
| | | |
| | | |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:03:07

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| User entered 'mg (mg)' | Thais Truffa (b) (4) | 18 Sep 2020 16:12:49 |
| | | |
| | | |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:03:07

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| User entered empty. | Thais Truffa (b) (4) | 18 Sep 2020 16:12:49 |
| | | |
| | | |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:03:07

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| User entered 'once daily (QD)' | Thais Truffa (b) (4) | 18 Sep 2020 16:12:49 |
| | | |
| | | |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:03:07

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| User entered empty. | Thais Truffa (b) (4) | 18 Sep 2020 16:12:49 |
| | | |
| | | |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:03:07

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| User entered 'Oral (ORAL)' | Thais Truffa (b) (4) | 18 Sep 2020 16:12:49 |
| | | |
| | | |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:03:07

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| User entered empty. | Thais Truffa (b) (4) | 18 Sep 2020 16:12:49 |
| | | |
| | | |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:03:07

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| User entered 'UN UNK 2000' | Thais Truffa (b) (4) | 18 Sep 2020 16:12:49 |
| | | |
| | | |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:03:07

Start date completely unknown

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| User entered '0' | Thais Truffa (b) (4) | 18 Sep 2020 16:12:49 |
| | | |
| | | |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:03:07

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Thais Truffa (b) (4) | 18 Sep 2020 16:12:49 |
| | | |
| | | |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:03:07

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| User entered empty. | Thais Truffa (b) (4) | 18 Sep 2020 16:12:49 |
| | | |
| | | |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:03:07

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| User entered 'No (N)' | Thais Truffa (b) (4) | 18 Sep 2020 16:12:49 |
| | | |
| | | |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:03:07

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 18 Sep 2020 16:12:49 |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:03:07

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 18 Sep 2020 16:12:49 |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:03:07

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 18 Sep 2020 16:12:49 |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:03:07

Name of Medication

| Audit | User | Time (GMT) |
|--|--|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003. | (b) (4) Coder Import (b) (4) (b) (4) | 19 Sep 2020 09:34:46 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 19 Sep 2020 09:34:46 |
| Data point term sent to Coder | System | 18 Sep 2020 16:16:34 |
| User entered 'Metropolol' | Thais Truffa (b) (4) (b) (4) (b) (4) | 18 Sep 2020 16:16:13 |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:03:07

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| User entered 'No (N)' | Thais Truffa (b) (4) | 18 Sep 2020 16:16:13 |
| | | |
| | | |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:03:07

[Indication](#)

| Audit | User | Time (GMT) |
|------------------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| User entered 'Atrial Fibrillation' | Thais Truffa (b) (4) | 18 Sep 2020 16:16:13 |
| | | |
| | | |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:03:07

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| User entered '12.5' | Thais Truffa (b) (4) | 18 Sep 2020 16:16:13 |
| | | |
| | | |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:03:07

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| User entered 'mg (mg)' | Thais Truffa (b) (4) | 18 Sep 2020 16:16:13 |
| | | |
| | | |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:03:07

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| User entered empty. | Thais Truffa (b) (4) | 18 Sep 2020 16:16:13 |
| | | |
| | | |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:03:07

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| User entered 'once daily (QD)' | Thais Truffa (b) (4) | 18 Sep 2020 16:16:13 |
| | | |
| | | |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:03:07

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| User entered empty. | Thais Truffa (b) (4) | 18 Sep 2020 16:16:13 |
| | | |
| | | |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:03:07

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| User entered 'Oral (ORAL)' | Thais Truffa (b) (4) | 18 Sep 2020 16:16:13 |
| | | |
| | | |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:03:07

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| User entered empty. | Thais Truffa (b) (4) | 18 Sep 2020 16:16:13 |
| | | |
| | | |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:03:07

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| User entered 'UN UNK 2020' | Thais Truffa (b) (4) | 18 Sep 2020 16:16:13 |
| | | |
| | | |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:03:07

Start date completely unknown

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| User entered '0' | Thais Truffa (b) (4) | 18 Sep 2020 16:16:13 |
| | | |
| | | |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:03:07

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Thais Truffa (b) (4) | 18 Sep 2020 16:16:13 |
| | | |
| | | |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:03:07

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| User entered empty. | Thais Truffa (b) (4) | 18 Sep 2020 16:16:13 |
| | | |
| | | |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:03:07

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| User entered 'No (N)' | Thais Truffa (b) (4) | 18 Sep 2020 16:16:13 |
| | | |
| | | |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:03:07

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 18 Sep 2020 16:16:13 |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:03:07

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 18 Sep 2020 16:16:13 |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:03:07

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 18 Sep 2020 16:16:13 |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:03:07

Name of Medication

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: LEUKOTRIENE RECEPTOR ANTAGONISTS, PRODUCT: MONTELUKAST - version WHODrug-Global-B3\\202003. | (b) (4) Coder Import (b) (4) | 18 Sep 2020 16:19:54 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 18 Sep 2020 16:19:54 |
| Data point term sent to Coder | System | 18 Sep 2020 16:18:39 |
| User entered 'Montelukast' | Thais Truffa (b) (4) (b) (4) | 18 Sep 2020 16:18:18 |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:03:07

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| User entered 'No (N)' | Thais Truffa (b) (4) | 18 Sep 2020 16:18:18 |
| | | |
| | | |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:03:07

[Indication](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 14:25:25 |
| Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'UPDATED' (Site from DM). | Albert Garcia (b) (4) (b) (4) | 31 Oct 2020 13:16:27 |
| User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM). | (b) (4), (b) (6) | 29 Oct 2020 21:01:48 |
| User entered 'Seasonal Allergy' | Thais Truffa (b) (4) | 18 Sep 2020 16:18:18 |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:03:07

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| User entered '10' | Thais Truffa (b) (4) | 18 Sep 2020 16:18:18 |
| | | |
| | | |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:03:07

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| User entered 'mg (mg)' | Thais Truffa (b) (4) | 18 Sep 2020 16:18:18 |
| | | |
| | | |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:03:07

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| User entered empty. | Thais Truffa (b) (4) | 18 Sep 2020 16:18:18 |
| | | |
| | | |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:03:07

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| User entered 'once daily (QD)' | Thais Truffa (b) (4) | 18 Sep 2020 16:18:18 |
| | | |
| | | |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:03:07

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| User entered empty. | Thais Truffa (b) (4) | 18 Sep 2020 16:18:18 |
| | | |
| | | |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:03:07

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| User entered 'Oral (ORAL)' | Thais Truffa (b) (4) | 18 Sep 2020 16:18:18 |
| | | |
| | | |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:03:07

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| User entered empty. | Thais Truffa (b) (4) | 18 Sep 2020 16:18:18 |
| | | |
| | | |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:03:07

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System). | System | 18 Sep 2020 16:30:40 |
| User entered 'UN UNK 2018' reason for change: Data Entry Error | Thais Truffa (b) (4) | 18 Sep 2020 16:30:40 |
| | | |
| User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System). | System | 18 Sep 2020 16:18:18 |
| User entered empty. | Thais Truffa (b) (4) | 18 Sep 2020 16:18:18 |
| | | |
| | | |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:03:07

Start date completely unknown

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| User entered '0' | Thais Truffa (b) (4) | 18 Sep 2020 16:18:18 |
| | | |
| | | |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:03:07

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Thais Truffa (b) (4) | 18 Sep 2020 16:18:18 |
| | | |
| | | |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:03:07

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| User entered empty. | Thais Truffa (b) (4) | 18 Sep 2020 16:18:18 |
| | | |
| | | |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:03:07

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| User entered 'No (N)' | Thais Truffa (b) (4) | 18 Sep 2020 16:18:18 |
| | | |
| | | |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:03:07

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 18 Sep 2020 16:18:18 |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:03:07

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 18 Sep 2020 16:18:18 |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:03:07

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 18 Sep 2020 16:18:18 |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:03:07

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| 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: OMEPRAZOLE - version WHODrug-Global-B3\\202003. | (b) (4) Coder Import (b) (4) | 18 Sep 2020 16:20:47 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 18 Sep 2020 16:20:47 |
| Data point term sent to Coder | System | 18 Sep 2020 16:19:42 |
| User entered 'Omeprazole' | Thais Truffa (b) (4) (b) (4) | 18 Sep 2020 16:19:31 |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:03:07

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| User entered 'No (N)' | Thais Truffa (b) (4) | 18 Sep 2020 16:19:31 |
| | | |
| | | |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:03:07

[Indication](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 14:26:06 |
| Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'UPDATED' (Site from DM). | Albert Garcia (b) (4) (b) (4) | 31 Oct 2020 13:16:17 |
| User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM). | (b) (4), (b) (6) | 29 Oct 2020 21:02:06 |
| User entered 'GERD' | Thais Truffa (b) (4) | 18 Sep 2020 16:19:31 |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:03:07

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| User entered '20' | Thais Truffa (b) (4) | 18 Sep 2020 16:19:31 |
| | | |
| | | |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:03:07

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| User entered 'mg (mg)' | Thais Truffa (b) (4) | 18 Sep 2020 16:19:31 |
| | | |
| | | |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:03:07

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| User entered empty. | Thais Truffa (b) (4) | 18 Sep 2020 16:19:31 |
| | | |
| | | |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:03:07

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| User entered 'once daily (QD)' | Thais Truffa (b) (4) | 18 Sep 2020 16:19:31 |
| | | |
| | | |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:03:07

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| User entered empty. | Thais Truffa (b) (4) | 18 Sep 2020 16:19:31 |
| | | |
| | | |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:03:07

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| User entered 'Oral (ORAL)' | Thais Truffa (b) (4) | 18 Sep 2020 16:19:31 |
| | | |
| | | |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:03:07

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| User entered empty. | Thais Truffa (b) (4) | 18 Sep 2020 16:19:31 |
| | | |
| | | |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:03:07

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| User entered 'UN UNK 2010' | Thais Truffa (b) (4) | 18 Sep 2020 16:19:31 |
| | | |
| | | |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:03:07

Start date completely unknown

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| User entered '0' | Thais Truffa (b) (4) | 18 Sep 2020 16:19:31 |
| | | |
| | | |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:03:07

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Thais Truffa (b) (4) | 18 Sep 2020 16:19:31 |
| | | |
| | | |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:03:07

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| User entered empty. | Thais Truffa (b) (4) | 18 Sep 2020 16:19:31 |
| | | |
| | | |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:03:07

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| User entered 'No (N)' | Thais Truffa (b) (4) | 18 Sep 2020 16:19:31 |
| | | |
| | | |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:03:07

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 18 Sep 2020 16:19:31 |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:03:07

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 18 Sep 2020 16:19:31 |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:03:07

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 18 Sep 2020 16:19:31 |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:03:07

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: TAMSULOSIN - version WHODrug-Global-B3\\202003. | (b) (4) Coder Import (b) (4) | 18 Sep 2020 16:22:53 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 18 Sep 2020 16:22:53 |
| Data point term sent to Coder | System | 18 Sep 2020 16:21:52 |
| User entered 'Tamsulosin' | Thais Truffa (b) (4) (b) (4) | 18 Sep 2020 16:21:07 |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:03:07

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| User entered 'No (N)' | Thais Truffa (b) (4) | 18 Sep 2020 16:21:07 |
| | | |
| | | |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:03:07

[Indication](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 14:26:50 |
| Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'UPDATED' (Site from DM). | Albert Garcia (b) (4) (b) (4) | 31 Oct 2020 13:16:06 |
| User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM). | (b) (4), (b) (6) | 29 Oct 2020 21:02:31 |
| User entered 'Overactive bladder' | Thais Truffa (b) (4) | 18 Sep 2020 16:21:07 |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:03:07

[Dose per administration](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered '0.4' reason for change: Data Entry Error | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 13:08:24 |
| User entered '4' | Thais Truffa (b) (4) | 18 Sep 2020 16:21:07 |
| | | |
| | | |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:03:07

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| User entered 'mg (mg)' | Thais Truffa (b) (4) | 18 Sep 2020 16:21:07 |
| | | |
| | | |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:03:07

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| User entered empty. | Thais Truffa (b) (4) | 18 Sep 2020 16:21:07 |
| | | |
| | | |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:03:07

[Frequency](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'twice daily (BID)' reason for change: Data Entry Error | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 13:08:24 |
| User entered 'once daily (QD)' | Thais Truffa (b) (4) | 18 Sep 2020 16:21:07 |
| | | |
| | | |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:03:07

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| User entered empty. | Thais Truffa (b) (4) | 18 Sep 2020 16:21:07 |
| | | |
| | | |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:03:07

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| User entered 'Oral (ORAL)' | Thais Truffa (b) (4) | 18 Sep 2020 16:21:07 |
| | | |
| | | |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:03:07

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| User entered empty. | Thais Truffa (b) (4) | 18 Sep 2020 16:21:07 |
| | | |
| | | |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:03:07

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| User entered 'UN UNK 2018' | Thais Truffa (b) (4) | 18 Sep 2020 16:21:07 |
| | | |
| | | |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:03:07

Start date completely unknown

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| User entered '0' | Thais Truffa (b) (4) | 18 Sep 2020 16:21:07 |
| | | |
| | | |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:03:07

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Thais Truffa (b) (4) | 18 Sep 2020 16:21:07 |
| | | |
| | | |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:03:07

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| User entered empty. | Thais Truffa (b) (4) | 18 Sep 2020 16:21:07 |
| | | |
| | | |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:03:07

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| User entered 'No (N)' | Thais Truffa (b) (4) | 18 Sep 2020 16:21:07 |
| | | |
| | | |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:03:07

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '2' | System | 28 Oct 2020 13:08:24 |
| User entered '1' | System | 18 Sep 2020 16:21:07 |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:03:07

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 18 Sep 2020 16:21:07 |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:03:07

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 18 Sep 2020 16:21:07 |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:03:07

Name of Medication

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 11:17:58 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User closed query 'Per MM, please confirm if the subject did not meet EC#9 (Has received or plans to receive a non-study vaccine within 28 days prior to or after any dose of IP (except for seasonal influenza vaccine which is not permitted within 14 days before or after any dose of IP). If met, please report as possible protocol deviation. (11 days after dose 2). (Site from DM). | (b) (4) (b) (4), (b) (6) | 18 Nov 2020 17:34:42 |
| Query 'Per MM, please confirm if the subject did not meet EC#9 (Has received or plans to receive a non-study vaccine within 28 days prior to or after any dose of IP (except for seasonal influenza vaccine which is not permitted within 14 days before or after any dose of IP). If met, please report as possible protocol deviation. (11 days after dose 2). answered with 'DATE ENTERED IS CORRECT. PD HAS BEEN COMPLETED AND PLACED INTO THE SUBJECT SOURCE CHART. ' (Site from DM). | Albert Garcia (b) (4) (b) (4) | 13 Nov 2020 13:26:06 |
| User opened query 'Per MM, please confirm if the subject did not meet EC#9 (Has received or plans to receive a non-study vaccine within 28 days prior to or after any dose of IP (except for seasonal influenza vaccine which is not permitted within 14 days before or after any dose of IP). If met, please report as possible protocol deviation. (11 days after dose 2). (Site from DM). | (b) (4), (b) (6) | 12 Nov 2020 18:35:38 |
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\202003. | Coder Import (b) (4) (b) (4) | 29 Oct 2020 17:56:22 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003. | Coder Import (b) (4) (b) (4) | 29 Oct 2020 17:56:22 |
| Data point term sent to Coder | System | 28 Oct 2020 15:08:16 |
| User entered 'INFLUENZA VACCINE' | (b) (4), (b) (6) | 28 Oct 2020 15:08:11 |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:03:07

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 11:17:58 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 15:08:11 |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:03:07

[Indication](#)

| Audit | User | Time (GMT) |
|-----------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 11:17:58 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'SEASONAL INFLUENZA' | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 15:08:11 |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:03:07

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 11:17:58 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'I' | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 15:08:11 |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:03:07

[Dose unit](#)

| Audit | User | Time (GMT) |
|------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 11:17:58 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'Other (OTHER)' | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 15:08:11 |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:03:07

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 11:17:58 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'INJECTION' | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 15:08:11 |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:03:07

[Frequency](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 11:17:58 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'once (ONCE)' | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 15:08:11 |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:03:07

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 11:17:58 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 15:08:11 |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:03:07

[Route of administration](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 11:17:58 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'Intramuscular (INTRAMUSCULAR)' | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 15:08:11 |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:03:07

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 11:17:58 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 15:08:11 |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:03:07

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 11:17:58 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered '16 Sep 2020' | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 15:08:11 |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:03:07

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 11:17:58 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 15:08:11 |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:03:07

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 11:17:58 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 15:08:11 |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:03:07

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 11:17:58 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered '16 Sep 2020' | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 15:08:11 |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:03:07

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 11:17:58 |
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 15:08:11 |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:03:07

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 11:17:58 |
| User entered empty. | System | 28 Oct 2020 15:08:11 |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:03:07

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 11:17:58 |
| User entered empty. | System | 28 Oct 2020 15:08:11 |

US3222013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:03:07

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 11:17:58 |
| User entered empty. | System | 28 Oct 2020 15:08:11 |

US3222013

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 16:03:07

[Were any concomitant procedures performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| User entered 'No (N)' | Amber Vasquez (b) (4) | 06 Aug 2020 19:31:52 |
| | (b) (4) | |

US3222013

Folder: SAE USA-US104-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[SAEID](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 18 Nov 2020 20:39:15 |
| User entered 'USA-US104-2020-MRNA-1273-P301000018' | System | 18 Nov 2020 20:37:49 |

US3222013

Folder: SAE USA-US104-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

Serious

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 18 Nov 2020 20:39:15 |
| User entered 'Yes (Y)' | System | 18 Nov 2020 20:37:49 |

US3222013

Folder: SAE USA-US104-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 18 Nov 2020 20:39:15 |
| User entered 'No (N)' | System | 18 Nov 2020 20:37:49 |

US3222013

Folder: SAE USA-US104-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 18 Nov 2020 20:39:15 |
| User entered 'No (N)' | System | 18 Nov 2020 20:37:49 |

US3222013

Folder: SAE USA-US104-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 18 Nov 2020 20:39:15 |
| User entered 'Yes (Y)' | System | 18 Nov 2020 20:37:49 |

US3222013

Folder: SAE USA-US104-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 18 Nov 2020 20:39:15 |
| User entered 'No (N)' | System | 18 Nov 2020 20:37:49 |

US3222013

Folder: SAE USA-US104-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 18 Nov 2020 20:39:15 |
| User entered 'No (N)' | System | 18 Nov 2020 20:37:49 |

US3222013

Folder: SAE USA-US104-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 18 Nov 2020 20:39:15 |
| User entered 'No (N)' | System | 18 Nov 2020 20:37:49 |

US3222013

Folder: SAE USA-US104-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| Un-reviewed for Safety. | System | 11 Dec 2020 17:31:08 |
| User entered 'Teresa' | System | 11 Dec 2020 17:31:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 11 Dec 2020 17:30:39 |
| | | |
| Un-reviewed for Safety. | System | 03 Dec 2020 16:51:06 |
| User entered 'Lisa' | System | 03 Dec 2020 16:51:06 |
| Reviewed for Safety. | (b) (4), (b) (6) | 18 Nov 2020 20:39:15 |
| | | |
| User entered 'Tracy' | System | 18 Nov 2020 20:37:49 |

US3222013

Folder: SAE USA-US104-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| Un-reviewed for Safety. | System | 11 Dec 2020 17:31:08 |
| User entered 'Becker' | System | 11 Dec 2020 17:31:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 11 Dec 2020 17:30:39 |
| | | |
| Un-reviewed for Safety. | System | 03 Dec 2020 16:51:06 |
| User entered 'Holloway' | System | 03 Dec 2020 16:51:06 |
| Reviewed for Safety. | (b) (4), (b) (6) | 18 Nov 2020 20:39:15 |
| | | |
| User entered 'Kowalski' | System | 18 Nov 2020 20:37:49 |

US3222013

Folder: SAE USA-US104-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|---------------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 11 Dec 2020 17:30:39 |
| User entered '6550 Mapleridge Street' | System | 03 Dec 2020 16:51:06 |

US3222013

Folder: SAE USA-US104-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[Site Address: City](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 11 Dec 2020 17:30:39 |
| User entered 'Houston' | System | 03 Dec 2020 16:51:06 |

US3222013

Folder: SAE USA-US104-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

Site Address: State

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| Un-reviewed for Safety. | System | 11 Dec 2020 17:31:08 |
| User entered empty. | System | 11 Dec 2020 17:31:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 11 Dec 2020 17:30:39 |
| | | |
| User entered 'TX' | System | 03 Dec 2020 16:51:06 |

US3222013

Folder: SAE USA-US104-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 11 Dec 2020 17:30:39 |
| User entered '77081' | System | 03 Dec 2020 16:51:06 |

US3222013

Folder: SAE USA-US104-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 03 Dec 2020 16:50:55 |
| User entered 'US' | System | 18 Nov 2020 20:39:21 |

US3222013

Folder: SAE USA-US104-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| User entered '3' | System | 11 Dec 2020 17:31:08 |
| User entered '2' | System | 03 Dec 2020 16:51:06 |
| User entered '1' | System | 18 Nov 2020 20:39:21 |

US3222013

Folder: SAE USA-US104-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[SAEID](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 18 Nov 2020 20:39:15 |
| User entered 'USA-US104-2020-MRNA-1273-P301000018' | System | 18 Nov 2020 20:37:49 |

US3222013

Folder: SAE USA-US104-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

Serious

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 18 Nov 2020 20:39:15 |
| User entered 'Yes (Y)' | System | 18 Nov 2020 20:37:49 |

US3222013

Folder: SAE USA-US104-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 18 Nov 2020 20:39:15 |
| User entered 'No (N)' | System | 18 Nov 2020 20:37:49 |

US3222013

Folder: SAE USA-US104-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 18 Nov 2020 20:39:15 |
| User entered 'No (N)' | System | 18 Nov 2020 20:37:49 |

US3222013

Folder: SAE USA-US104-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 18 Nov 2020 20:39:15 |
| User entered 'Yes (Y)' | System | 18 Nov 2020 20:37:49 |

US3222013

Folder: SAE USA-US104-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 18 Nov 2020 20:39:15 |
| User entered 'No (N)' | System | 18 Nov 2020 20:37:49 |

US3222013

Folder: SAE USA-US104-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 18 Nov 2020 20:39:15 |
| User entered 'No (N)' | System | 18 Nov 2020 20:37:49 |

US3222013

Folder: SAE USA-US104-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 18 Nov 2020 20:39:15 |
| User entered 'No (N)' | System | 18 Nov 2020 20:37:49 |

US3222013

Folder: SAE USA-US104-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| Un-reviewed for Safety. | System | 11 Dec 2020 17:31:08 |
| User entered 'Teresa' | System | 11 Dec 2020 17:31:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 11 Dec 2020 17:30:39 |
| | | |
| Un-reviewed for Safety. | System | 03 Dec 2020 16:51:06 |
| User entered 'Lisa' | System | 03 Dec 2020 16:51:06 |
| Reviewed for Safety. | (b) (4), (b) (6) | 18 Nov 2020 20:39:15 |
| | | |
| User entered 'Tracy' | System | 18 Nov 2020 20:37:49 |

US3222013

Folder: SAE USA-US104-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| Un-reviewed for Safety. | System | 11 Dec 2020 17:31:08 |
| User entered 'Becker' | System | 11 Dec 2020 17:31:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 11 Dec 2020 17:30:39 |
| | | |
| Un-reviewed for Safety. | System | 03 Dec 2020 16:51:06 |
| User entered 'Holloway' | System | 03 Dec 2020 16:51:06 |
| Reviewed for Safety. | (b) (4), (b) (6) | 18 Nov 2020 20:39:15 |
| | | |
| User entered 'Kowalski' | System | 18 Nov 2020 20:37:49 |

US3222013

Folder: SAE USA-US104-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|---------------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 11 Dec 2020 17:30:39 |
| User entered '6550 Mapleridge Street' | System | 03 Dec 2020 16:51:06 |

US3222013

Folder: SAE USA-US104-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[Site Address: City](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 11 Dec 2020 17:30:39 |
| User entered 'Houston' | System | 03 Dec 2020 16:51:06 |

US3222013

Folder: SAE USA-US104-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

Site Address: State

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| Un-reviewed for Safety. | System | 11 Dec 2020 17:31:08 |
| User entered empty. | System | 11 Dec 2020 17:31:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 11 Dec 2020 17:30:39 |
| | | |
| User entered 'TX' | System | 03 Dec 2020 16:51:06 |

US3222013

Folder: SAE USA-US104-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 11 Dec 2020 17:30:39 |
| User entered '77081' | System | 03 Dec 2020 16:51:06 |

US3222013

Folder: SAE USA-US104-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 03 Dec 2020 16:50:55 |
| User entered 'US' | System | 18 Nov 2020 20:39:21 |

US3222013

Folder: SAE USA-US104-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| User entered '3' | System | 11 Dec 2020 17:31:08 |
| User entered '2' | System | 03 Dec 2020 16:51:06 |
| User entered '1' | System | 18 Nov 2020 20:39:21 |

US3222013

Folder: SAE USA-US104-2020-MRNA-1273-P301000018

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:03:07

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered '18/Nov/2020 20:39' | (b) (4) System | 18 Nov 2020 20:39:21 |

US3222013

Folder: SAE USA-US104-2020-MRNA-1273-P301000018

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:03:07

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) | 16 Feb 2021 16:27:05 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 03 Dec 2020 16:50:55 |
| User entered 'I' | (b) (4), (b) (6) | 18 Nov 2020 20:39:21 |

US3222013

Folder: SAE USA-US104-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[SAEID](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 18 Nov 2020 20:39:15 |
| User entered 'USA-US104-2020-MRNA-1273-P301000018' | System | 18 Nov 2020 20:37:49 |

US3222013

Folder: SAE USA-US104-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

Serious

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 18 Nov 2020 20:39:15 |
| User entered 'Yes (Y)' | System | 18 Nov 2020 20:37:49 |

US3222013

Folder: SAE USA-US104-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 18 Nov 2020 20:39:15 |
| User entered 'No (N)' | System | 18 Nov 2020 20:37:49 |

US3222013

Folder: SAE USA-US104-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 18 Nov 2020 20:39:15 |
| User entered 'No (N)' | System | 18 Nov 2020 20:37:49 |

US3222013

Folder: SAE USA-US104-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 18 Nov 2020 20:39:15 |
| User entered 'Yes (Y)' | System | 18 Nov 2020 20:37:49 |

US3222013

Folder: SAE USA-US104-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 18 Nov 2020 20:39:15 |
| User entered 'No (N)' | System | 18 Nov 2020 20:37:49 |

US3222013

Folder: SAE USA-US104-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 18 Nov 2020 20:39:15 |
| User entered 'No (N)' | System | 18 Nov 2020 20:37:49 |

US3222013

Folder: SAE USA-US104-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 18 Nov 2020 20:39:15 |
| User entered 'No (N)' | System | 18 Nov 2020 20:37:49 |

US3222013

Folder: SAE USA-US104-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| Un-reviewed for Safety. | System | 11 Dec 2020 17:31:08 |
| User entered 'Teresa' | System | 11 Dec 2020 17:31:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 11 Dec 2020 17:30:39 |
| | | |
| Un-reviewed for Safety. | System | 03 Dec 2020 16:51:06 |
| User entered 'Lisa' | System | 03 Dec 2020 16:51:06 |
| Reviewed for Safety. | (b) (4), (b) (6) | 18 Nov 2020 20:39:15 |
| | | |
| User entered 'Tracy' | System | 18 Nov 2020 20:37:49 |

US3222013

Folder: SAE USA-US104-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| Un-reviewed for Safety. | System | 11 Dec 2020 17:31:08 |
| User entered 'Becker' | System | 11 Dec 2020 17:31:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 11 Dec 2020 17:30:39 |
| | | |
| Un-reviewed for Safety. | System | 03 Dec 2020 16:51:06 |
| User entered 'Holloway' | System | 03 Dec 2020 16:51:06 |
| Reviewed for Safety. | (b) (4), (b) (6) | 18 Nov 2020 20:39:15 |
| | | |
| User entered 'Kowalski' | System | 18 Nov 2020 20:37:49 |

US3222013

Folder: SAE USA-US104-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|---------------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 11 Dec 2020 17:30:39 |
| User entered '6550 Mapleridge Street' | System | 03 Dec 2020 16:51:06 |

US3222013

Folder: SAE USA-US104-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[Site Address: City](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 11 Dec 2020 17:30:39 |
| User entered 'Houston' | System | 03 Dec 2020 16:51:06 |

US3222013

Folder: SAE USA-US104-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

Site Address: State

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| Un-reviewed for Safety. | System | 11 Dec 2020 17:31:08 |
| User entered empty. | System | 11 Dec 2020 17:31:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 11 Dec 2020 17:30:39 |
| | | |
| User entered 'TX' | System | 03 Dec 2020 16:51:06 |

US3222013

Folder: SAE USA-US104-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 11 Dec 2020 17:30:39 |
| User entered '77081' | System | 03 Dec 2020 16:51:06 |

US3222013

Folder: SAE USA-US104-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 03 Dec 2020 16:50:55 |
| User entered 'US' | System | 18 Nov 2020 20:39:21 |

US3222013

Folder: SAE USA-US104-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| User entered '3' | System | 11 Dec 2020 17:31:08 |
| User entered '2' | System | 03 Dec 2020 16:51:06 |
| User entered '1' | System | 18 Nov 2020 20:39:21 |

US3222013

Folder: SAE USA-US104-2020-MRNA-1273-P301000018

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:03:07

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered '03/Dec/2020 11:51' | (b) (4) System | 03 Dec 2020 16:51:06 |

US3222013

Folder: SAE USA-US104-2020-MRNA-1273-P301000018

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:03:07

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) | 16 Feb 2021 16:27:05 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 11 Dec 2020 17:30:39 |
| User entered 'I' | (b) (4), (b) (6) | 03 Dec 2020 16:51:06 |

US3222013

Folder: SAE USA-US104-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[SAEID](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 18 Nov 2020 20:39:15 |
| User entered 'USA-US104-2020-MRNA-1273-P301000018' | System | 18 Nov 2020 20:37:49 |

US3222013

Folder: SAE USA-US104-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

Serious

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 18 Nov 2020 20:39:15 |
| User entered 'Yes (Y)' | System | 18 Nov 2020 20:37:49 |

US3222013

Folder: SAE USA-US104-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 18 Nov 2020 20:39:15 |
| User entered 'No (N)' | System | 18 Nov 2020 20:37:49 |

US3222013

Folder: SAE USA-US104-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 18 Nov 2020 20:39:15 |
| User entered 'No (N)' | System | 18 Nov 2020 20:37:49 |

US3222013

Folder: SAE USA-US104-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 18 Nov 2020 20:39:15 |
| User entered 'Yes (Y)' | System | 18 Nov 2020 20:37:49 |

US3222013

Folder: SAE USA-US104-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 18 Nov 2020 20:39:15 |
| User entered 'No (N)' | System | 18 Nov 2020 20:37:49 |

US3222013

Folder: SAE USA-US104-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 18 Nov 2020 20:39:15 |
| User entered 'No (N)' | System | 18 Nov 2020 20:37:49 |

US3222013

Folder: SAE USA-US104-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 18 Nov 2020 20:39:15 |
| User entered 'No (N)' | System | 18 Nov 2020 20:37:49 |

US3222013

Folder: SAE USA-US104-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| Un-reviewed for Safety. | System | 11 Dec 2020 17:31:08 |
| User entered 'Teresa' | System | 11 Dec 2020 17:31:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 11 Dec 2020 17:30:39 |
| | | |
| Un-reviewed for Safety. | System | 03 Dec 2020 16:51:06 |
| User entered 'Lisa' | System | 03 Dec 2020 16:51:06 |
| Reviewed for Safety. | (b) (4), (b) (6) | 18 Nov 2020 20:39:15 |
| | | |
| User entered 'Tracy' | System | 18 Nov 2020 20:37:49 |

US3222013

Folder: SAE USA-US104-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| Un-reviewed for Safety. | System | 11 Dec 2020 17:31:08 |
| User entered 'Becker' | System | 11 Dec 2020 17:31:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 11 Dec 2020 17:30:39 |
| | | |
| Un-reviewed for Safety. | System | 03 Dec 2020 16:51:06 |
| User entered 'Holloway' | System | 03 Dec 2020 16:51:06 |
| Reviewed for Safety. | (b) (4), (b) (6) | 18 Nov 2020 20:39:15 |
| | | |
| User entered 'Kowalski' | System | 18 Nov 2020 20:37:49 |

US3222013

Folder: SAE USA-US104-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|---------------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 11 Dec 2020 17:30:39 |
| User entered '6550 Mapleridge Street' | System | 03 Dec 2020 16:51:06 |

US3222013

Folder: SAE USA-US104-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[Site Address: City](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 11 Dec 2020 17:30:39 |
| User entered 'Houston' | System | 03 Dec 2020 16:51:06 |

US3222013

Folder: SAE USA-US104-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

Site Address: State

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| Un-reviewed for Safety. | System | 11 Dec 2020 17:31:08 |
| User entered empty. | System | 11 Dec 2020 17:31:08 |
| Reviewed for Safety. | (b) (4), (b) (6) | 11 Dec 2020 17:30:39 |
| | | |
| User entered 'TX' | System | 03 Dec 2020 16:51:06 |

US3222013

Folder: SAE USA-US104-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 11 Dec 2020 17:30:39 |
| User entered '77081' | System | 03 Dec 2020 16:51:06 |

US3222013

Folder: SAE USA-US104-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 03 Dec 2020 16:50:55 |
| User entered 'US' | System | 18 Nov 2020 20:39:21 |

US3222013

Folder: SAE USA-US104-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 16:03:07

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| | (b) (4) | |
| User entered '3' | System | 11 Dec 2020 17:31:08 |
| User entered '2' | System | 03 Dec 2020 16:51:06 |
| User entered '1' | System | 18 Nov 2020 20:39:21 |

US3222013

Folder: SAE USA-US104-2020-MRNA-1273-P301000018

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:03:07

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------|----------------------|
| User signature succeeded. | Bruce Rankin (b) (4) | 16 Feb 2021 16:27:05 |
| User entered '11/Dec/2020 12:31' | (b) (4) System | 11 Dec 2020 17:31:08 |

US3222013

Folder: SAE USA-US104-2020-MRNA-1273-P301000018

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:03:07

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) | 16 Feb 2021 16:27:05 |
| User entered 'I' | (b) (4) (b) (4), (b) (6) | 11 Dec 2020 17:31:08 |