

US3712094 (Prod: Alliance for Multispecialty Research, LLC)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:25:14

All time stamps listed in this document are displayed in GMT

US3712094

Form: Participant Creation

Data signed: (b) (4) 05 Apr 2021 00:19:20

Generated On: 10 Jun 2021 09:25:14

[Participant ID](#)

US3712094

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

US3712094

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 00:21:47

Generated On: 10 Jun 2021 09:25:14

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 14 SEP 2020 |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/> |
| | Clinic <input checked="" type="radio"/> |
| Folder OID | SCRN |

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 13 Feb 2021 00:20:48

Generated On: 10 Jun 2021 09:25:14

| | |
|---|--|
| Date of Birth (MMM yyyy) | (b) (6) 1978 |
| Age | 41 |
| Age Units | YEARS |
| Age (Derived) | 41 |
| Sex | Female <input checked="" type="radio"/> Male <input 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 |

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 13 Feb 2021 00:20:49

Generated On: 10 Jun 2021 09:25:14

| | |
|---|--|
| Date of Informed Consent (<i>dd MMM yyyy</i>) | 14 SEP 2020 |
| Month and Year of Informed Consent (derived) | SEP 2020 |
| Year of Informed Consent (derived) | 2020 |
| Protocol Version | Amendment 1 <input type="radio"/> Amendment 2 <input type="radio"/> Amendment 3 <input checked="" type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/> |
| Was participant enrolled in the study? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| If No, indicate reason for screen fail | Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/> |
| If reason for screen fail is Other, specify | |
| Was this participant screened previously? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| If Yes, previous participant number | |
| Enrollment Trigger | 1 |

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 13 Feb 2021 00:21:47

Generated On: 10 Jun 2021 09:25:14

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 13 Feb 2021 00:21:47

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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) 13 Feb 2021 00:21:47

Generated On: 10 Jun 2021 09:25:14

| | |
|---|--|
| Condition | WISDOM TEETH IMPACTION |
| Start date (dd MMM yyyy) | UN UNK 2000 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) | UN UNK 2000 |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 2000 |
| Start Year (derived) | 2000 |
| Stop Month and Year (derived) | JAN 2000 |
| Stop Year (derived) | 2000 |

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 13 Feb 2021 00:21:47

Generated On: 10 Jun 2021 09:25:14

| | |
|---|--|
| Condition | WISDOM TEETH EXTRACTION |
| Start date (dd MMM yyyy) | UN UNK 2000 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) | UN UNK 2000 |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 2000 |
| Start Year (derived) | 2000 |
| Stop Month and Year (derived) | JAN 2000 |
| Stop Year (derived) | 2000 |

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 13 Feb 2021 00:21:47

Generated On: 10 Jun 2021 09:25:14

| | |
|---|--|
| Condition | BIPOLAR DISORDER TYPE II |
| Start date (dd MMM yyyy) | UN UNK 2012 |
| 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 2012 |
| Start Year (derived) | 2012 |
| Stop Month and Year (derived) | _____ |
| Stop Year (derived) | _____ |

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 13 Feb 2021 00:21:47

Generated On: 10 Jun 2021 09:25:14

| | |
|---|--|
| Condition | BREAST IMPLANTS |
| Start date (dd MMM yyyy) | UN UNK 2007 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) | UN UNK 2007 |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 2007 |
| Start Year (derived) | 2007 |
| Stop Month and Year (derived) | JAN 2007 |
| Stop Year (derived) | 2007 |

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 00:21:47

Generated On: 10 Jun 2021 09:25:14

| | |
|---|---------------------------------------|
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (<i>dd MMM yyyy</i>) | 14 SEP 2020 |
| Time of assessment (<i>00:00-23:59</i>) | 10:11 (24 HR) |
| Vital Signs Date and Time (derived) | 14 SEP 2020 10:11 |
| Height (<i>xxx.x</i>) | 169.0 cm |
| Weight (<i>xxx.x</i>) | 70.0 kg |
| BMI (<i>xxx.x</i>) | 24.50895 kg/m ² |
| BMI units | KG/M2 |
| Temperature (<i>xxx.x</i>) | 37.3 C |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (<i>xxx</i>) | 66 beats/min |
| Pulse units | BPM |
| Respiratory Rate (<i>xxx</i>) | 16 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (<i>xxx</i>) | 114 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (<i>xxx</i>) | 75 mmHg |
| Diastolic Blood Pressure units | MMHG |
| Height (derived) | |
| Weight (derived) | |

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 00:21:47

Generated On: 10 Jun 2021 09:25:14

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 SEP 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 13 Feb 2021 00:20:48

Generated On: 10 Jun 2021 09:25:14

Date of assessment (*dd MMM yyyy*) 14 SEP 2020

Is the participant of childbearing potential? Yes ☒
No ☐

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

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

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Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 13 Feb 2021 00:21:47

Generated On: 10 Jun 2021 09:25:14

| | |
|-------------------------------------|---|
| Was the pregnancy test performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of test (<i>dd MMM yyyy</i>) | 14 SEP 2020 |
| Test performed | Urine <input checked="" type="radio"/> |
| | Serum <input type="radio"/> |
| Result | Positive <input type="radio"/> |
| | Negative <input checked="" type="radio"/> |
| Was FSH sample collected? | Yes <input type="radio"/> |
| | No <input checked="" type="radio"/> |
| Collection date | |
| Collection time | |
| Collection date and time (derived) | |

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 00:21:47

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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

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) 13 Feb 2021 00:21:47

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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 | True |
| Specify | LIVES WITH PEOPLE WHO ARE AT OCCUPATIONAL RISK OF EXPOSURE |

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 00:21:47

Generated On: 10 Jun 2021 09:25:14

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 21 SEP 2020 |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/> |
| | Clinic <input checked="" type="radio"/> |
| Folder OID | VISIT1 |

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 13 Feb 2021 00:21:47

Generated On: 10 Jun 2021 09:25:14

What was the date of randomization? (dd MMM yyyy) 21 SEP 2020

What was the participant's randomization number? 115005

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 13 Feb 2021 00:21:47

Generated On: 10 Jun 2021 09:25:14

| | |
|--------|----------|
| Height | 169.0 cm |
| Weight | 70.8 kg |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 00:21:47

Generated On: 10 Jun 2021 09:25:14

| | |
|-------------------------------------|--|
| Height | 169.0 cm |
| Weight | 70.8 kg |
| 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) | 21 SEP 2020 |
| Time of assessment (00:00-23:59) | 11:18 (24 HR) |
| Vital Signs Date and Time (derived) | 21 SEP 2020 11:18 |
| 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) | 67 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 14 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 110 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 76 mmHg |
| Diastolic Blood Pressure units | MMHG |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 00:21:47

Generated On: 10 Jun 2021 09:25:14

| | |
|-------------------------------------|---|
| Height | 169.0 cm |
| Weight | 70.8 kg |
| 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) | 21 SEP 2020 |
| Time of assessment (00:00-23:59) | 13:00 (24 HR) |
| Vital Signs Date and Time (derived) | 21 SEP 2020 13:00 |
| Temperature (xxx.x) | 36.5 C |
| Route of measurement | Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/> |
| If Other, specify | |
| Pulse (xxx) | 59 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 16 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 121 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 83 mmHg |
| Diastolic Blood Pressure units | MMHG |

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 00:21:47

Generated On: 10 Jun 2021 09:25:14

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 SEP 2020

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

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 13 Feb 2021 00:21:47

Generated On: 10 Jun 2021 09:25:14

| | |
|-------------------------------------|---|
| Was the pregnancy test performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of test (<i>dd MMM yyyy</i>) | 21 SEP 2020 |
| Test performed | Urine <input checked="" type="radio"/> |
| | Serum <input type="radio"/> |
| Result | Positive <input type="radio"/> |
| | Negative <input checked="" type="radio"/> |
| Was FSH sample collected? | Yes <input type="radio"/> |
| | No <input checked="" type="radio"/> |
| Collection date | |
| Collection time | |
| Collection date and time (derived) | |

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 00:21:47

Generated On: 10 Jun 2021 09:25:14

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) 21 SEP 2020

What was the treatment time? (00:00-23:59) 12:25 (24 HR)

Treatment Date and Time (derived) 21 SEP 2020 12:25

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) 13 Feb 2021 00:21:47

Generated On: 10 Jun 2021 09:25:14

| | |
|------------------------------------|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (dd MMM yyyy) | 21 SEP 2020 |
| Collection time (00:00-23:59) | 11:34 (24 HR) |
| Collection date and time (derived) | 21 SEP 2020 11:34 |

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 20 Feb 2021 17:12:15

Generated On: 10 Jun 2021 09:25:14

| | | | |
|--|---------------------------|--|------------------------------------|
| Collection date (<i>dd MMM yyyy</i>) | | | 21 SEP 2020 |
| Lab Test | Was the sample collected? | Collection time (<i>00:00 - 23:59</i>) | Collection date and time (derived) |
| Nasopharyngeal Swab 1 | Yes | 11:35 | 21 SEP 2020 11:35 |
| Nasopharyngeal Swab 2 | No | | |

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:21:47

Generated On: 10 Jun 2021 09:25:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒
No ☐

Please record your **TEMPERATURE** in °F

97.7 °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 21 SEP 2020 12:56

PC Open Date & Time 21 SEP 2020 12:45

PC Close Date & Time 21 SEP 2020 15:15

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 SEP 2020 19:20

PC Open Date & Time

21 SEP 2020 16:10

PC Close Date & Time

22 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:25:14

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

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 SEP 2020 21:27

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3712094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °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

23 SEP 2020 12:03

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3712094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 SEP 2020 12:00

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3712094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °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

25 SEP 2020 16:06

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3712094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °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

26 SEP 2020 18:56

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3712094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 SEP 2020 16:48

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3712094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:25:14

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

21 SEP 2020 12:57

PC Open Date & Time

21 SEP 2020 12:45

PC Close Date & Time

21 SEP 2020 15:15

US3712094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:25:14

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

21 SEP 2020 19:20

PC Open Date & Time

21 SEP 2020 16:10

PC Close Date & Time

22 SEP 2020 11:59

US3712094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:25:14

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

22 SEP 2020 21:27

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3712094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:25:14

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

23 SEP 2020 12:03

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3712094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:25:14

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

24 SEP 2020 12:00

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3712094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:25:14

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

25 SEP 2020 16:07

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3712094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:25:14

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

26 SEP 2020 18:56

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3712094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:25:14

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

27 SEP 2020 16:48

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3712094

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:25:14

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 ☐

US3712094

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:25:14

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 21 SEP 2020 12:57 |
| PC Open Date & Time | 21 SEP 2020 12:45 |
| PC Close Date & Time | 21 SEP 2020 15:15 |

US3712094

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:25:14

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 ☐

US3712094

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:25:14

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 21 SEP 2020 19:21 |
| PC Open Date & Time | 21 SEP 2020 16:10 |
| PC Close Date & Time | 22 SEP 2020 11:59 |

US3712094

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:25:14

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 ☒

US3712094

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:25:14

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 22 SEP 2020 21:27 |
| PC Open Date & Time | 22 SEP 2020 12:00 |
| PC Close Date & Time | 23 SEP 2020 11:59 |

US3712094

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3712094

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:25:14

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 23 SEP 2020 12:04 |
| PC Open Date & Time | 23 SEP 2020 12:00 |
| PC Close Date & Time | 24 SEP 2020 11:59 |

US3712094

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:25:14

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 ☒

US3712094

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:25:14

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 24 SEP 2020 12:01 |
| PC Open Date & Time | 24 SEP 2020 12:00 |
| PC Close Date & Time | 25 SEP 2020 11:59 |

US3712094

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:25:14

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 ☒

US3712094

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:25:14

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 25 SEP 2020 16:07 |
| PC Open Date & Time | 25 SEP 2020 12:00 |
| PC Close Date & Time | 26 SEP 2020 11:59 |

US3712094

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:25:14

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 ☒

US3712094

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:25:14

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 26 SEP 2020 18:57 |
| PC Open Date & Time | 26 SEP 2020 12:00 |
| PC Close Date & Time | 27 SEP 2020 11:59 |

US3712094

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:25:14

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 ☒

US3712094

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:25:14

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 27 SEP 2020 16:49 |
| PC Open Date & Time | 27 SEP 2020 12:00 |
| PC Close Date & Time | 28 SEP 2020 11:59 |

US3712094

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:20:48

Generated On: 10 Jun 2021 09:25:14

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3712094

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:20:48

Generated On: 10 Jun 2021 09:25:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712094

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 23:29:00

Generated On: 10 Jun 2021 09:25:14

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 06 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3712094

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:20:48

Generated On: 10 Jun 2021 09:25:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712094

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:20:48

Generated On: 10 Jun 2021 09:25:14

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 12 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3712094

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:20:48

Generated On: 10 Jun 2021 09:25:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712094

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 00:21:47

Generated On: 10 Jun 2021 09:25:14

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

| | |
|--------------------------|-------------|
| Visit date (dd MMM yyyy) | 19 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 | VISIT2 |
|------------|--------|

US3712094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 00:21:47

Generated On: 10 Jun 2021 09:25:14

| | |
|-------------------------------------|---|
| 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) | 19 OCT 2020 |
| Time of assessment (00:00-23:59) | 10:22 (24 HR) |
| Vital Signs Date and Time (derived) | 19 OCT 2020 10:22 |
| Temperature (xxx.x) | 37.2 C |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 71 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 16 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 116 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 68 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3712094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 00:21:47

Generated On: 10 Jun 2021 09:25:14

| | |
|-------------------------------------|--|
| 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) | 19 OCT 2020 |
| Time of assessment (00:00-23:59) | 11:51 (24 HR) |
| Vital Signs Date and Time (derived) | 19 OCT 2020 11:51 |
| Temperature (xxx.x) | 37.0 C |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 83 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 16 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 105 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 72 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3712094

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 00:21:47

Generated On: 10 Jun 2021 09:25:14

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.

US3712094

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 13 Feb 2021 00:21:47

Generated On: 10 Jun 2021 09:25:14

Was the pregnancy test performed? Yes ☒
No ☐

Date of test (dd MMM yyyy) 19 OCT 2020

Test performed Urine ☒
Serum ☐

Result Positive ☐
Negative ☒

Was FSH sample collected? Yes ☐
No ☒

Collection date _____
Collection time _____
Collection date and time (derived) _____

US3712094

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 00:21:47

Generated On: 10 Jun 2021 09:25:14

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

What was the treatment time? (00:00-23:59) 11:16 (24 HR)

Treatment Date and Time (derived) 19 OCT 2020 11:16

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

US3712094

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 00:21:47

Generated On: 10 Jun 2021 09:25:14

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

19 OCT 2020

Collection time (00:00-23:59)

10:46 (24 HR)

Collection date and time (derived)

19 OCT 2020 10:46

US3712094

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 20 Feb 2021 17:12:15

Generated On: 10 Jun 2021 09:25:14

| | | | |
|-------------------------------|---------------------------|---------------------------------|------------------------------------|
| Collection date (dd MMM yyyy) | | | 19 OCT 2020 |
| Lab Test | Was the sample collected? | Collection time (00:00 - 23:59) | Collection date and time (derived) |
| Nasopharyngeal Swab 1 | Yes | 10:49 | 19 OCT 2020 10:49 |
| Nasopharyngeal Swab 2 | No | | |

US3712094

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:21:47

Generated On: 10 Jun 2021 09:25:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 OCT 2020 11:50

PC Open Date & Time

19 OCT 2020 11:36

PC Close Date & Time

19 OCT 2020 14:06

US3712094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.6 °F

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

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

| | |
|----------------------|-------------------|
| PC Time Stamp | 19 OCT 2020 22:17 |
| PC Open Date & Time | 19 OCT 2020 15:01 |
| PC Close Date & Time | 20 OCT 2020 11:59 |

US3712094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:25:14

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

20 OCT 2020 21:11

PC Open Date & Time

20 OCT 2020 12:00

PC Close Date & Time

21 OCT 2020 11:59

US3712094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 OCT 2020 17:28

PC Open Date & Time

21 OCT 2020 12:00

PC Close Date & Time

22 OCT 2020 11:59

US3712094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 OCT 2020 20:28

PC Open Date & Time

22 OCT 2020 12:00

PC Close Date & Time

23 OCT 2020 11:59

US3712094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:25:14

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

23 OCT 2020 18:19

PC Open Date & Time

23 OCT 2020 12:00

PC Close Date & Time

24 OCT 2020 11:59

US3712094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:25:14

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.

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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

24 OCT 2020 19:38

PC Open Date & Time

24 OCT 2020 12:00

PC Close Date & Time

25 OCT 2020 11:59

US3712094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 OCT 2020 22:07

PC Open Date & Time

25 OCT 2020 12:00

PC Close Date & Time

26 OCT 2020 11:59

US3712094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:25:14

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

19 OCT 2020 11:47

PC Open Date & Time

19 OCT 2020 11:36

PC Close Date & Time

19 OCT 2020 14:06

US3712094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

19 OCT 2020 22:17

PC Open Date & Time

19 OCT 2020 15:01

PC Close Date & Time

20 OCT 2020 11:59

US3712094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

20 OCT 2020 21:11

PC Open Date & Time

20 OCT 2020 12:00

PC Close Date & Time

21 OCT 2020 11:59

US3712094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:25:14

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

21 OCT 2020 17:28

PC Open Date & Time

21 OCT 2020 12:00

PC Close Date & Time

22 OCT 2020 11:59

US3712094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

22 OCT 2020 20:29

PC Open Date & Time

22 OCT 2020 12:00

PC Close Date & Time

23 OCT 2020 11:59

US3712094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:25:14

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

23 OCT 2020 18:19

PC Open Date & Time

23 OCT 2020 12:00

PC Close Date & Time

24 OCT 2020 11:59

US3712094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

24 OCT 2020 19:38

PC Open Date & Time

24 OCT 2020 12:00

PC Close Date & Time

25 OCT 2020 11:59

US3712094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:25:14

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

25 OCT 2020 22:07

PC Open Date & Time

25 OCT 2020 12:00

PC Close Date & Time

26 OCT 2020 11:59

US3712094

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:25:14

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 ☐

US3712094

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:25:14

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 19 OCT 2020 11:47 |
| PC Open Date & Time | 19 OCT 2020 11:36 |
| PC Close Date & Time | 19 OCT 2020 14:06 |

US3712094

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:25:14

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 ☐

US3712094

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:25:14

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 19 OCT 2020 22:18 |
| PC Open Date & Time | 19 OCT 2020 15:01 |
| PC Close Date & Time | 20 OCT 2020 11:59 |

US3712094

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:25:14

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
EAB) (1725)

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US3712094

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:25:14

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

US3712094

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:25:14

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 ☒

US3712094

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:25:14

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 21 OCT 2020 17:29 |
| PC Open Date & Time | 21 OCT 2020 12:00 |
| PC Close Date & Time | 22 OCT 2020 11:59 |

US3712094

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:25:14

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)

US3712094

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:25:14

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 22 OCT 2020 20:29 |
| PC Open Date & Time | 22 OCT 2020 12:00 |
| PC Close Date & Time | 23 OCT 2020 11:59 |

US3712094

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:25:14

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

101 of 2073

EAB) (1725)

US3712094

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:25:14

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 23 OCT 2020 18:20 |
| PC Open Date & Time | 23 OCT 2020 12:00 |
| PC Close Date & Time | 24 OCT 2020 11:59 |

US3712094

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:25:14

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 ☒

US3712094

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:25:14

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 24 OCT 2020 19:39 |
| PC Open Date & Time | 24 OCT 2020 12:00 |
| PC Close Date & Time | 25 OCT 2020 11:59 |

US3712094

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:25:14

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 ☒

US3712094

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:25:14

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 25 OCT 2020 22:07 |
| PC Open Date & Time | 25 OCT 2020 12:00 |
| PC Close Date & Time | 26 OCT 2020 11:59 |

US3712094

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 23:29:00

Generated On: 10 Jun 2021 09:25:14

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3712094

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:20:48

Generated On: 10 Jun 2021 09:25:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712094

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:20:48

Generated On: 10 Jun 2021 09:25:14

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 02 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3712094

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:20:48

Generated On: 10 Jun 2021 09:25:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712094

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:20:48

Generated On: 10 Jun 2021 09:25:14

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 09 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3712094

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:20:48

Generated On: 10 Jun 2021 09:25:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712094

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 00:21:47

Generated On: 10 Jun 2021 09:25:14

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 16 NOV 2020 |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/> |
| | Clinic <input checked="" type="radio"/> |
| Folder OID | VISIT3 |

US3712094

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 00:21:47

Generated On: 10 Jun 2021 09:25:14

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) _____

US3712094

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 00:21:47

Generated On: 10 Jun 2021 09:25:14

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.

US3712094

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 00:21:47

Generated On: 10 Jun 2021 09:25:14

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

16 NOV 2020

Collection time (00:00-23:59)

11:15 (24 HR)

Collection date and time (derived)

16 NOV 2020 11:15

US3712094

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:21:47

Generated On: 10 Jun 2021 09:25:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

| TIMEPOINT | DAY 61 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> 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"/> |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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

[Patient Cloud Close Date & Time](#)

22 NOV 2020 23:59

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

| TIMEPOINT | DAY 68 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input 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 | 28 NOV 2020 17:59:29 |
| Patient Cloud Open Date & Time | 25 NOV 2020 00:01 |
| Patient Cloud Close Date & Time | 29 NOV 2020 23:59 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

DAY 75

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

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 00:01:20

Patient Cloud Open Date & Time

02 DEC 2020 00:01

Patient Cloud Close Date & Time

06 DEC 2020 23:59

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

| TIMEPOINT | DAY 82 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input 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 | 09 DEC 2020 09:54:58 |
| Patient Cloud Open Date & Time | 09 DEC 2020 00:01 |
| Patient Cloud Close Date & Time | 13 DEC 2020 23:59 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

DAY 89

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 DEC 2020 11:59:30

Patient Cloud Open Date & Time

16 DEC 2020 00:01

Patient Cloud Close Date & Time

20 DEC 2020 23:59

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

| TIMEPOINT | DAY 96 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> 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 | 23 DEC 2020 15:30:27 |
| Patient Cloud Open Date & Time | 23 DEC 2020 00:01 |
| Patient Cloud Close Date & Time | 27 DEC 2020 23:59 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 DEC 2020 14:29:21

Patient Cloud Open Date & Time

30 DEC 2020 00:01

Patient Cloud Close Date & Time

03 JAN 2021 23:59

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 JAN 2021 12:00:44

Patient Cloud Open Date & Time

06 JAN 2021 00:01

Patient Cloud Close Date & Time

10 JAN 2021 23:59

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

| TIMEPOINT | DAY 117 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input 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 | 15 JAN 2021 12:17:52 |
| Patient Cloud Open Date & Time | 13 JAN 2021 00:01 |
| Patient Cloud Close Date & Time | 17 JAN 2021 23:59 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 JAN 2021 12:00:30

Patient Cloud Open Date & Time

20 JAN 2021 00:01

Patient Cloud Close Date & Time

24 JAN 2021 23:59

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 JAN 2021 00:40:14

Patient Cloud Open Date & Time

27 JAN 2021 00:01

Patient Cloud Close Date & Time

31 JAN 2021 23:59

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 FEB 2021 13:32:44

Patient Cloud Open Date & Time

03 FEB 2021 00:01

Patient Cloud Close Date & Time

07 FEB 2021 23:59

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 FEB 2021 12:00:24

Patient Cloud Open Date & Time

10 FEB 2021 00:01

Patient Cloud Close Date & Time

14 FEB 2021 23:59

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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

19 FEB 2021 12:04:03

Patient Cloud Open Date & Time

17 FEB 2021 00:01

Patient Cloud Close Date & Time

21 FEB 2021 23:59

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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

28 FEB 2021 12:59:13

Patient Cloud Open Date & Time

24 FEB 2021 00:01

Patient Cloud Close Date & Time

28 FEB 2021 23:59

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

| | |
|---|--|
| 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 | 03 MAR 2021 00:02:39 |
| Patient Cloud Open Date & Time | 03 MAR 2021 00:01 |
| Patient Cloud Close Date & Time | 07 MAR 2021 23:59 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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

13 MAR 2021 08:29:33

Patient Cloud Open Date & Time

10 MAR 2021 00:01

Patient Cloud Close Date & Time

14 MAR 2021 23:59

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 MAR 2021 12:32:06

Patient Cloud Open Date & Time

17 MAR 2021 00:01

Patient Cloud Close Date & Time

21 MAR 2021 23:59

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 MAR 2021 00:02:35

Patient Cloud Open Date & Time

24 MAR 2021 00:01

Patient Cloud Close Date & Time

28 MAR 2021 23:59

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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

01 APR 2021 11:10:05

Patient Cloud Open Date & Time

31 MAR 2021 00:01

Patient Cloud Close Date & Time

04 APR 2021 23:59

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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

07 APR 2021 15:50:10

Patient Cloud Open Date & Time

07 APR 2021 00:01

Patient Cloud Close Date & Time

11 APR 2021 23:59

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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

15 APR 2021 03:13:19

Patient Cloud Open Date & Time

14 APR 2021 00:01

Patient Cloud Close Date & Time

18 APR 2021 23:59

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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

23 APR 2021 12:15:40

Patient Cloud Open Date & Time

21 APR 2021 00:01

Patient Cloud Close Date & Time

25 APR 2021 23:59

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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

28 APR 2021 00:03:26

Patient Cloud Open Date & Time

28 APR 2021 00:01

Patient Cloud Close Date & Time

02 MAY 2021 23:59

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

DAY 229

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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

[Patient Cloud Close Date & Time](#)

09 MAY 2021 23:59

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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

[Patient Cloud Close Date & Time](#)

16 MAY 2021 23:59

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

DAY 243

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

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

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

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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

[Patient Cloud Close Date & Time](#)

23 MAY 2021 23:59

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

| TIMEPOINT | DAY 250 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> 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"/> |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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

[Patient Cloud Close Date & Time](#)

30 MAY 2021 23:59

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

DAY 257

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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

[Patient Cloud Close Date & Time](#)

06 JUN 2021 23:59

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

| TIMEPOINT | DAY 264 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> 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"/> |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2021 23:59

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

DAY 271

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2021 23:59

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

DAY 278

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

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

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

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

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

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

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

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

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2021 23:59

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

| 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"/> |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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

[Patient Cloud Close Date & Time](#)

11 JUL 2021 23:59

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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°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 ☐

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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 ☐

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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

[Patient Cloud Close Date & Time](#)

25 JUL 2021 23:59

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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 ☐

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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

28 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2021 23:59

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

| 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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <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"/> |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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

[Patient Cloud Close Date & Time](#)

08 AUG 2021 23:59

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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 ☐

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

15 AUG 2021 23:59

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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 ☐

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2021 23:59

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

| 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"/> |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

29 AUG 2021 23:59

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

| 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"/> |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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 ☐

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 SEP 2021 00:01 |
| Patient Cloud Close Date & Time | 12 SEP 2021 23:59 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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

[Patient Cloud Close Date & Time](#)

19 SEP 2021 23:59

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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 ☐

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 SEP 2021 00:01 |
| Patient Cloud Close Date & Time | 26 SEP 2021 23:59 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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 ☐

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2021 23:59

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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 ☐

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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

[Patient Cloud Close Date & Time](#)

10 OCT 2021 23:59

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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 ☐

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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

[Patient Cloud Close Date & Time](#)

17 OCT 2021 23:59

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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 ☐

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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

| | |
|---|-------------------|
| Patient Cloud Close Date & Time | 24 OCT 2021 23:59 |
|---|-------------------|

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

| 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"/> |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

| 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"/> |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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

[Patient Cloud Close Date & Time](#)

07 NOV 2021 23:59

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

| TIMEPOINT | DAY 425 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="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"/> |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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

[Patient Cloud Close Date & Time](#)

21 NOV 2021 23:59

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

DAY 432

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

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

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

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

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

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

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

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

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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

[Patient Cloud Close Date & Time](#)

28 NOV 2021 23:59

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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 ☐

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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

[Patient Cloud Close Date & Time](#)

05 DEC 2021 23:59

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

| 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"/> |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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

[Patient Cloud Close Date & Time](#)

12 DEC 2021 23:59

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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 ☐

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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

[Patient Cloud Close Date & Time](#)

19 DEC 2021 23:59

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

| 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°F/38°C) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01 |
| Patient Cloud Close Date & Time | 26 DEC 2021 23:59 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

| TIMEPOINT | DAY 467 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> 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"/> |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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

[Patient Cloud Close Date & Time](#)

02 JAN 2022 23:59

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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°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 ☐

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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

[Patient Cloud Close Date & Time](#)

09 JAN 2022 23:59

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

| 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"/> |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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

[Patient Cloud Close Date & Time](#)

16 JAN 2022 23:59

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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 ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-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 ☐

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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

[Patient Cloud Close Date & Time](#)

23 JAN 2022 23:59

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

DAY 495

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

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

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

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

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

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

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

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

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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

[Patient Cloud Close Date & Time](#)

30 JAN 2022 23:59

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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 ☐

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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

[Patient Cloud Close Date & Time](#)

06 FEB 2022 23:59

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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 ☐

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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

[Patient Cloud Close Date & Time](#)

13 FEB 2022 23:59

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

| TIMEPOINT | DAY 516 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="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"/> |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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

[Patient Cloud Close Date & Time](#)

20 FEB 2022 23:59

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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 ☐

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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

[Patient Cloud Close Date & Time](#)

27 FEB 2022 23:59

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

| 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="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"/> |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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

[Patient Cloud Close Date & Time](#)

06 MAR 2022 23:59

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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 ☐

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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

[Patient Cloud Close Date & Time](#)

13 MAR 2022 23:59

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

DAY 544

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

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

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

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

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

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

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

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

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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

[Patient Cloud Close Date & Time](#)

20 MAR 2022 23:59

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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 ☐

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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 ☐

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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

[Patient Cloud Close Date & Time](#)

03 APR 2022 23:59

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

DAY 565

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

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

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

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

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

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

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

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

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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

[Patient Cloud Close Date & Time](#)

10 APR 2022 23:59

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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 ☐

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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

[Patient Cloud Close Date & Time](#)

17 APR 2022 23:59

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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 ☐

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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

[Patient Cloud Close Date & Time](#)

24 APR 2022 23:59

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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 ☐

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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

[Patient Cloud Close Date & Time](#)

01 MAY 2022 23:59

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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 ☐

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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

[Patient Cloud Close Date & Time](#)

08 MAY 2022 23:59

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

| 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"/> |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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

[Patient Cloud Close Date & Time](#)

15 MAY 2022 23:59

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

| TIMEPOINT | DAY 607 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> 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"/> |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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

[Patient Cloud Close Date & Time](#)

22 MAY 2022 23:59

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

| TIMEPOINT | DAY 614 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> 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"/> |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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

[Patient Cloud Close Date & Time](#)

29 MAY 2022 23:59

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

| 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"/> |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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

[Patient Cloud Close Date & Time](#)

05 JUN 2022 23:59

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

| 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"/> |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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

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12 JUN 2022 23:59

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

DAY 635

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

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

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

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

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

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

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

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

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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

[Patient Cloud Close Date & Time](#)

19 JUN 2022 23:59

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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 ☐

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JUN 2022 23:59

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

DAY 649

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

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

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

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

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

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

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

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

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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

[Patient Cloud Close Date & Time](#)

03 JUL 2022 23:59

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

DAY 656

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

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

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

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

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

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

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

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

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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

[Patient Cloud Close Date & Time](#)

10 JUL 2022 23:59

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

| 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 <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"/> |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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

[Patient Cloud Close Date & Time](#)

17 JUL 2022 23:59

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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

[Patient Cloud Close Date & Time](#)

24 JUL 2022 23:59

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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

[Patient Cloud Close Date & Time](#)

31 JUL 2022 23:59

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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 ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-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 ☐

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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

[Patient Cloud Close Date & Time](#)

07 AUG 2022 23:59

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

| 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"/> |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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

[Patient Cloud Close Date & Time](#)

14 AUG 2022 23:59

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

DAY 698

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

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

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

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

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

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

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

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

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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

[Patient Cloud Close Date & Time](#)

21 AUG 2022 23:59

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

| TIMEPOINT | DAY 705 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> 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"/> |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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

| | |
|---|-------------------|
| Patient Cloud Close Date & Time | 28 AUG 2022 23:59 |
|---|-------------------|

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

| TIMEPOINT | DAY 712 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> 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"/> |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

04 SEP 2022 23:59

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

| 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"/> |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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

[Patient Cloud Close Date & Time](#)

11 SEP 2022 23:59

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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 ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-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 ☐

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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

[Patient Cloud Close Date & Time](#)

18 SEP 2022 23:59

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

| 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"/> |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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

[Patient Cloud Close Date & Time](#)

25 SEP 2022 23:59

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

| 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"/> |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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

28 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

02 OCT 2022 23:59

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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°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 ☐

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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

[Patient Cloud Close Date & Time](#)

16 OCT 2022 23:59

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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 ☐

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

23 OCT 2022 23:59

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

DAY 768

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

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

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

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

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

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

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

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

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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

| | |
|---|-------------------|
| Patient Cloud Close Date & Time | 30 OCT 2022 23:59 |
|---|-------------------|

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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 ☐

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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

[Patient Cloud Close Date & Time](#)

06 NOV 2022 23:59

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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 ☐

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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

[Patient Cloud Close Date & Time](#)

13 NOV 2022 23:59

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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 ☐

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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

[Patient Cloud Close Date & Time](#)

20 NOV 2022 23:59

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

| 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"/> |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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

[Patient Cloud Close Date & Time](#)

27 NOV 2022 23:59

US3712094

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:25:14

| Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other? | Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache? | Date & Time of Submission |
|---|--|---------------------------|
| No | | 28 FEB 2021 12:59:23 |

US3712094

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 10 Mar 2021 02:31:13

Generated On: 10 Jun 2021 09:25:14

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3712094

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 10 Mar 2021 02:31:13

Generated On: 10 Jun 2021 09:25:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712094

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 00:19:21

Generated On: 10 Jun 2021 09:25:14

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 16 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3712094

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 00:19:21

Generated On: 10 Jun 2021 09:25:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712094

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 00:19:21

Generated On: 10 Jun 2021 09:25:14

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 15 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3712094

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 00:19:21

Generated On: 10 Jun 2021 09:25:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712094

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 00:19:21

Generated On: 10 Jun 2021 09:25:14

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 15 MAR 2021

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

Comments

If Contact Not Made, please provide Comments

US3712094

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 00:19:21

Generated On: 10 Jun 2021 09:25:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712094

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 23 Apr 2021 21:40:01

Generated On: 10 Jun 2021 09:25:14

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

| | |
|--------------------------|-------------|
| Visit date (dd MMM yyyy) | 19 APR 2021 |
|--------------------------|-------------|

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

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

US3712094

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 23 Apr 2021 21:40:01

Generated On: 10 Jun 2021 09:25:14

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) _____

US3712094

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Apr 2021 21:40:01

Generated On: 10 Jun 2021 09:25:14

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.

US3712094

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Apr 2021 21:40:01

Generated On: 10 Jun 2021 09:25:14

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

| | |
|-------------------------------|-------------|
| Collection date (dd MMM yyyy) | 19 APR 2021 |
|-------------------------------|-------------|

| | |
|-------------------------------|---------------|
| Collection time (00:00-23:59) | 14:49 (24 HR) |
|-------------------------------|---------------|

| | |
|------------------------------------|-------------------|
| Collection date and time (derived) | 19 APR 2021 14:49 |
|------------------------------------|-------------------|

US3712094

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 23 Apr 2021 21:40:01

Generated On: 10 Jun 2021 09:25:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712094

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:25:14

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

US3712094

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:25:14

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3712094

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:25:14

| | |
|--|---|
| 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"/> |

US3712094

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 09:25:14

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3712094

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

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 00:19:21

Generated On: 10 Jun 2021 09:25:14

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 30 DEC 2020 |
| 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 |

US3712094

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

Form: Unblinding

Data signed: (b) (4) 05 Apr 2021 00:19:21

Generated On: 10 Jun 2021 09:25:14

| | |
|---|---|
| Date of updated informed consent (<i>dd MMM yyyy</i>) | 30 DEC 2020 |
| N/A - Subject Unblinded under Amendment 5 and Discontinued from Study | False |
| Was the participant unblinded? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Under what version of the Protocol was the Participant unblinded? | Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/> |
| Date of unblinding (<i>dd MMM yyyy</i>) | 30 DEC 2020 |
| Participant randomization assignment | mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> |
| Actual Dose 1 | mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/> |
| Actual Dose 2 | mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/> |
| Will participant receive mRNA-1273? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Placebo Only Flag | 1 |
| Continuing with mRNA-1273 | 1 |

US3712094

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 05 Apr 2021 00:19:21

Generated On: 10 Jun 2021 09:25:14

| | |
|-------------|----------|
| Height | 168.2 cm |
| Weight | 67.6 kg |
| BMI (xxx.x) | 23.89432 |

US3712094

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 05 Apr 2021 00:19:21

Generated On: 10 Jun 2021 09:25:14

| | |
|-------------------------------------|--|
| Height | 168.2 cm |
| Weight | 67.6 kg |
| BMI (xxx.x) | 23.89432 |
| Timepoint | Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/> |
| Were vital signs assessed? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 30 DEC 2020 |
| Time of assessment (00:00-23:59) | 15:00 (24 HR) |
| Vital Signs Date and Time (derived) | 30 DEC 2020 15:00 |
| 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) | 79 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 14 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 111 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 71 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3712094

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Apr 2021 00:19:21

Generated On: 10 Jun 2021 09:25:14

| | |
|-------------------------------------|--|
| Height | 168.2 cm |
| Weight | 67.6 kg |
| BMI (xxx.x) | 23.89432 |
| Timepoint | Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/> |
| Were vital signs assessed? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 30 DEC 2020 |
| Time of assessment (00:00-23:59) | 15:45 (24 HR) |
| Vital Signs Date and Time (derived) | 30 DEC 2020 15:45 |
| 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) | 77 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 14 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 105 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 72 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3712094

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

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 00:19:20

Generated On: 10 Jun 2021 09:25:14

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

30 DEC 2020

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

US3712094

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

Form: Pregnancy Test

Data signed: (b) (4) 05 Apr 2021 00:19:20

Generated On: 10 Jun 2021 09:25:14

| | |
|-------------------------------------|---|
| Was the pregnancy test performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of test (<i>dd MMM yyyy</i>) | 30 DEC 2020 |
| Test performed | Urine <input checked="" type="radio"/> |
| | Serum <input type="radio"/> |
| Result | Positive <input type="radio"/> |
| | Negative <input checked="" type="radio"/> |
| Was FSH sample collected? | Yes <input type="radio"/> |
| | No <input checked="" type="radio"/> |
| Collection date | |
| Collection time | |
| Collection date and time (derived) | |

US3712094

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

Form: Exposure

Data signed: (b) (4) 05 Apr 2021 00:19:20

Generated On: 10 Jun 2021 09:25:14

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? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 30 DEC 2020

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

Treatment Date and Time (derived) 30 DEC 2020 15:15

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

US3712094

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Apr 2021 00:19:20

Generated On: 10 Jun 2021 09:25:14

| | |
|------------------------------------|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (dd MMM yyyy) | 30 DEC 2020 |
| Collection time (00:00-23:59) | 14:27 (24 HR) |
| Collection date and time (derived) | 30 DEC 2020 14:27 |

US3712094

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 05 Apr 2021 00:19:20

Generated On: 10 Jun 2021 09:25:14

| | |
|------------------------------------|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (dd MMM yyyy) | 30 DEC 2020 |
| Collection time (00:00 - 23:59) | 14:32 |
| Collection Date and Time (derived) | 30 DEC 2020 14:32 |

US3712094

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

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 00:19:20

Generated On: 10 Jun 2021 09:25:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712094

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 00:19:21

Generated On: 10 Jun 2021 09:25:14

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

06 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3712094

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 00:19:21

Generated On: 10 Jun 2021 09:25:14

| | |
|--|--------------------------------------|
| Is the participant continuing to the next visit? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Continuing Flag | 1 |
| OLD29 Placebo Flag | 1 |

US3712094

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 00:19:20

Generated On: 10 Jun 2021 09:25:14

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 01 FEB 2021 |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/> |
| | Clinic <input checked="" type="radio"/> |
| Folder OID | OLD29 |

US3712094

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 05 Apr 2021 00:19:20

Generated On: 10 Jun 2021 09:25:14

| | |
|-------------------------------------|---|
| 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) | 01 FEB 2021 |
| Time of assessment (00:00-23:59) | 11:35 (24 HR) |
| Vital Signs Date and Time (derived) | 01 FEB 2021 11:35 |
| Temperature (xxx.x) | 37.1 C |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 72 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 17 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 102 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 68 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3712094

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Apr 2021 00:19:20

Generated On: 10 Jun 2021 09:25:14

| | |
|-------------------------------------|---|
| 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) | 01 FEB 2021 |
| Time of assessment (00:00-23:59) | 12:36 (24 HR) |
| Vital Signs Date and Time (derived) | 01 FEB 2021 12:36 |
| Temperature (xxx.x) | 36.9 C |
| Route of measurement | Oral <input checked="" type="checkbox"/> |
| | Axillary <input type="checkbox"/> |
| | Other <input type="checkbox"/> |
| If Other, specify | |
| Pulse (xxx) | 97 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 16 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 114 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 70 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3712094

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 00:19:20

Generated On: 10 Jun 2021 09:25:14

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.

US3712094

Folder: OL-D29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 05 Apr 2021 00:19:20

Generated On: 10 Jun 2021 09:25:14

| | |
|-------------------------------------|---|
| Was the pregnancy test performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of test (<i>dd MMM yyyy</i>) | 01 FEB 2021 |
| Test performed | Urine <input checked="" type="radio"/> |
| | Serum <input type="radio"/> |
| Result | Positive <input type="radio"/> |
| | Negative <input checked="" type="radio"/> |
| Was FSH sample collected? | Yes <input type="radio"/> |
| | No <input checked="" type="radio"/> |
| Collection date | |
| Collection time | |
| Collection date and time (derived) | |

US3712094

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 05 Apr 2021 00:19:20

Generated On: 10 Jun 2021 09:25:14

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? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 01 FEB 2021

What was the treatment time? (00:00-23:59) 12:06 (24 HR)

Treatment Date and Time (derived) 01 FEB 2021 12:06

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

US3712094

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 00:19:20

Generated On: 10 Jun 2021 09:25:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712094

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 00:19:21

Generated On: 10 Jun 2021 09:25:14

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3712094

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 00:19:21

Generated On: 10 Jun 2021 09:25:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712094

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 00:19:20

Generated On: 10 Jun 2021 09:25:14

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 08 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 | OLD57 |

US3712094

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 00:19:20

Generated On: 10 Jun 2021 09:25:14

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) _____

US3712094

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 00:19:20

Generated On: 10 Jun 2021 09:25:14

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.

US3712094

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Apr 2021 00:19:20

Generated On: 10 Jun 2021 09:25:14

| | |
|------------------------------------|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (dd MMM yyyy) | 08 MAR 2021 |
| Collection time (00:00-23:59) | 10:45 (24 HR) |
| Collection date and time (derived) | 08 MAR 2021 10:45 |

US3712094

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 12 Mar 2021 22:21:26

Generated On: 10 Jun 2021 09:25:14

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3712094

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 18 Apr 2021 23:29:00

Generated On: 10 Jun 2021 09:25:14

| | |
|--|--|
| AEID | USA-US068-2021-MRNA-1273-P30 1000015 |
| Adverse event | APPENDICITIS |
| 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) | 20 DEC 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) | 22 DEC 2020 |
| End time (00:00-23:59) | |
| AE End Date and Time (derived) | |
| Severity | Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input 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) | 21 DEC 2020 |
| Hospital Discharge Date (dd MMM yyyy) | 22 DEC 2020 |
| Admitted to ICU? | Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/> |

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 18 Apr 2021 23:29:00

Generated On: 10 Jun 2021 09:25:14

| | |
|--|---|
| Number of Days in ICU | |
| Persistent or significant disability or incapacity | False |
| Congenital anomaly or birth defect | False |
| Other medically important event | False |
| Relationship to investigational product | Not Related <input checked="" type="radio"/> 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 Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/> |
| Other action taken (check all that apply) | |
| None | False |
| Concomitant Medication | True |
| Concomitant Procedure | True |
| Outcome | Fatal <input type="radio"/> 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 | |

US3712094

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 18 Apr 2021 23:29:00

Generated On: 10 Jun 2021 09:25:14

SUBJECT ARRIVED AT
PARKWEST MEDICAL CENTER
ON 21 DEC 2020 WITH RIGHT
LOWER QUADRANT
ABDOMINAL PAIN THAT
STARTED ON 20 DEC 2020
EARLY AM WITH VOMITING.
CT SCAN WAS OBTAINED IN ED
AND SHOWED ACUTE
APPENDICITIS WITH APPENDIX
FLUID FILLED WITH
NUMEROUS APPENDICOLITHS
AT THE TIP, MEASURING UP TO
7MM, WITHOUT PERFORATION
AND SUBJECT WAS PREPARED
FOR EMERGENT SURGERY
WHICH SHE HAD ON 21 DEC
2020.

LAB WORK RESULTED AS
FOLLOWED: NEUTROPHIL: 91.3,
LYMPHOCYTE: 4.0, WBC: 16.9,
LIPASE: 25, HCG URINE:
NEGATIVE, UA WBC: 11,
SARS-COV-2 ANTIGEN:
NEGATIVE.

PATHOLOGY REPORT:
FORMALIN "APPENDIX" IS A
12CM IN LENGTH X 0.7CM IN
AVERAGE DIAMETER
VERIFORM APPENDIX WITH
ASSOCIATED FAT. THE SEROSA
IS PURPLE TO PINK AND
FOCALLY ROUGHENED. THE
SOFT YELLOW MUCOSAL
SURFACES

US3712094

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 18 Apr 2021 23:29:00

Generated On: 10 Jun 2021 09:25:14

ARE FOCALLY HEMORRHAGIC.
THE NONPERFORATING WALL
AVERAGE 0.2CM IN
THICKNESS. THERE ARE NO
CONTENTS OR FECALITH IN
THE LUMEN. THE MARGIN IS
INKED BLUE. A1
REPRESENTATIVE SECTIONS.
PERFORMED 21 DEC 2020.

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

US3712094

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 18 Apr 2021 23:29:00

Generated On: 10 Jun 2021 09:25:14

| | |
|--|--|
| AEID | |
| Adverse event | UTERINE FIBROIDS |
| 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) | 21 DEC 2020 |
| Start time (00:00-23:59) | |
| AE start date and time (derived) | |
| Ongoing? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| If not Ongoing, end date (dd MMM yyyy) | |
| End time (00:00-23:59) | |
| AE End Date and Time (derived) | |
| Severity | Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/> |
| Is the adverse event serious? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| AE is serious due To (check all that apply) | |
| Death | False |
| Life threatening | False |
| Requires inpatient or prolongation of existing Hospitalization | False |
| Hospital Admission Date (dd MMM yyyy) | |
| Hospital Discharge Date (dd MMM yyyy) | |
| Admitted to ICU? | Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/> |
| Number of Days in ICU | |

US3712094

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 18 Apr 2021 23:29:00

Generated On: 10 Jun 2021 09:25:14

| | |
|--|---|
| 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 | True |
| Concomitant Medication | False |
| Concomitant Procedure | False |
| Outcome | Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" type="radio"/> Unknown <input type="radio"/> |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____ | |
| Narrative _____ | |
| Serious Adverse Event Derived (CSA Programming Field Only) | 0 |
| Medically Attended AE Derived (CSA Programming Field Only) | 1 |
| Admitted to ICU Derived (CSA Programming Field Only) | _____ |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 05 Apr 2021 00:19:20

Generated On: 10 Jun 2021 09:25:14

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

Yes ☒

No ☐

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

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 05 Apr 2021 00:19:20

Generated On: 10 Jun 2021 09:25:14

Name of Medication VENLAFAXINE

Prophylaxis Yes ☐
No ☒

Indication BIPOLAR DISORDER TYPE II

Dose per administration 150

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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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 05 Apr 2021 00:19:20

Generated On: 10 Jun 2021 09:25:14

| | | |
|--|--------------------------|----------------------------------|
| | 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 2016 | |
| 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"/> |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 05 Apr 2021 00:19:20

Generated On: 10 Jun 2021 09:25:14

Name of Medication SEROQUEL

Prophylaxis Yes ☐
No ☒

Indication BIPOLAR DISORDER TYPE II

Dose per administration 350

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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EAB) (1725)

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 05 Apr 2021 00:19:20

Generated On: 10 Jun 2021 09:25:14

| | | |
|--|--------------------------|----------------------------------|
| | 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 SEP 2017 | |
| 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"/> |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 05 Apr 2021 00:19:20

Generated On: 10 Jun 2021 09:25:14

Name of Medication TRILEPTAL

Prophylaxis Yes ☐
No ☒

Indication BIPOLAR DISORDER TYPE II

Dose per administration 300

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 (3)

Data signed: (b) (4) 05 Apr 2021 00:19:20

Generated On: 10 Jun 2021 09:25:14

| | | |
|--|--------------------------|----------------------------------|
| | 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 2015 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | 1 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 05 Apr 2021 00:19:20

Generated On: 10 Jun 2021 09:25:14

Name of Medication GABAPENTIN

Prophylaxis Yes ☐
No ☒

Indication BIPOLAR DISORDER TYPE II

Dose per administration 600

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 (4)

Data signed: (b) (4) 05 Apr 2021 00:19:20

Generated On: 10 Jun 2021 09:25:14

| | | |
|--|--------------------------|----------------------------------|
| | 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 2015 | |
| 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"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 05 Apr 2021 00:19:20

Generated On: 10 Jun 2021 09:25:14

Name of Medication PARAGARD

Prophylaxis Yes ☒
No ☐

Indication CONTRACEPTION

Dose per administration 1

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

If dose unit is Other, specify IUD

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 CONTINUOUS

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 (5)

Data signed: (b) (4) 05 Apr 2021 00:19:20

Generated On: 10 Jun 2021 09:25:14

| | | |
|--|--------------------------|----------------------------------|
| | Intramuscular | <input 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 checked="" type="radio"/> |
| If route of administration is Other, specify | INTRAUTERINE | |
| 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) | | |
| Interval Dosage Unit Number (derived) | | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 05 Apr 2021 00:19:20

Generated On: 10 Jun 2021 09:25:14

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication INFLUENZA VACCINE

Dose per administration 0.5

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 (6)

Data signed: (b) (4) 05 Apr 2021 00:19:20

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| | | |
|--|--------------------------|----------------------------------|
| | 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) | | 09 NOV 2020 |
| Start date completely unknown | | False |
| Ongoing? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) | | 09 NOV 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"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 05 Apr 2021 00:19:20

Generated On: 10 Jun 2021 09:25:14

Name of Medication ZOFRAN

Prophylaxis Yes ☐
No ☒

Indication NAUSEA (APPENDICITIS)

Dose per administration 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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 05 Apr 2021 00:19:20

Generated On: 10 Jun 2021 09:25:14

| | | |
|--|--------------------------|-------------------------------------|
| | 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) | | 22 DEC 2020 |
| Start date completely unknown | | False |
| Ongoing? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) 22 DEC 2020 | | |
| Was this medication taken for solicited event? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived) _____ | | |
| Interval Dosage Unit Number (derived) _____ | | |
| Interval Dosage Definition (derived) | 802 | <input type="checkbox"/> |
| | 803 | <input type="checkbox"/> |
| | 804 | <input type="checkbox"/> |

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 05 Apr 2021 00:19:20

Generated On: 10 Jun 2021 09:25:14

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 05 Apr 2021 00:19:20

Generated On: 10 Jun 2021 09:25:14

| Procedure/Surgery date (dd MMM yyyy) | Procedure/Surgery | Indication | If indication is Other, specify |
|---|-------------------|---------------|---------------------------------|
| 21 DEC 2020 | APPENDECTOMY | Adverse Event | |

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:25:14

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

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

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:25:14

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 ☐

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Folder: SAE USA-US068-2021-MRNA-1273-P301000015

Form: Safety Report Form

Data signed: (b) (4) 05 Apr 2021 00:19:21

Generated On: 10 Jun 2021 09:25:14

| | |
|--|--|
| SAEID | USA-US068-2021-MRNA-1273-P301000015 |
| 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 | WILLIAM |
| Investigator's Last Name | SMITH |
| Site Address: Street | |
| Site Address: City | |
| Site Address: State | |
| Site Address: Postal Code | (b) (4) |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 4 |

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Folder: SAE USA-US068-2021-MRNA-1273-P301000015

Form: Safety Report Form (1)

Data signed: (b) (4) 05 Apr 2021 00:19:21

Generated On: 10 Jun 2021 09:25:14

| | |
|---|--|
| SAEID | USA-US068-2021-MRNA-1273-P301000015 |
| 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 | WILLIAM |
| Investigator's Last Name | SMITH |
| Site Address: Street | |
| Site Address: City | |
| Site Address: State | |
| Site Address: Postal Code | (b) (4) |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 4 |
| Date of submission (Pre-filled from custom function) | 24/FEB/2021 09:43 |
| 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 |

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Folder: SAE USA-US068-2021-MRNA-1273-P301000015

Form: Safety Report Form (2)

Data signed: (b) (4) 05 Apr 2021 00:19:21

Generated On: 10 Jun 2021 09:25:14

| | |
|---|--|
| SAEID | USA-US068-2021-MRNA-1273-P301000015 |
| 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 | WILLIAM |
| Investigator's Last Name | SMITH |
| Site Address: Street | |
| Site Address: City | |
| Site Address: State | |
| Site Address: Postal Code | (b) (4) |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 4 |
| Date of submission (Pre-filled from custom function) | 26/FEB/2021 09:22 |
| 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 |

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Folder: SAE USA-US068-2021-MRNA-1273-P301000015

Form: Safety Report Form (3)

Data signed: (b) (4) 05 Apr 2021 00:19:21

Generated On: 10 Jun 2021 09:25:14

| | |
|---|--|
| SAEID | USA-US068-2021-MRNA-1273-P301000015 |
| 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 | WILLIAM |
| Investigator's Last Name | SMITH |
| Site Address: Street | |
| Site Address: City | |
| Site Address: State | |
| Site Address: Postal Code | (b) (4) |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 4 |
| Date of submission (Pre-filled from custom function) | 22/MAR/2021 12:16 |
| Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge. | True |

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Folder: SAE USA-US068-2021-MRNA-1273-P301000015

Form: Safety Report Form (4)

Data signed: (b) (4) 05 Apr 2021 00:19:21

Generated On: 10 Jun 2021 09:25:14

| | |
|---|--|
| SAEID | USA-US068-2021-MRNA-1273-P301000015 |
| 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 | WILLIAM |
| Investigator's Last Name | SMITH |
| Site Address: Street | |
| Site Address: City | |
| Site Address: State | |
| Site Address: Postal Code | (b) (4) |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 4 |
| Date of submission (Pre-filled from custom function) | 30/MAR/2021 12:14 |
| Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge. | True |

Audit

US3712094 (Prod: Alliance for Multispecialty Research, LLC)

US3712094

Form: Participant Creation

Generated On: 10 Jun 2021 09:25:14

[Participant ID](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 15:01:40 |
| User entered 'US3712094' | RWS_ENDPOINT ENDPOINT (b) (4) | 14 Sep 2020 14:10:03 |

US3712094

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:25:14

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:24 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 17:59:04 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 14 Sep 2020 21:50:45 |

US3712094

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:24 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 17:59:04 |
| User entered '14 SEP 2020' | RWS_ENDPOINT ENDPOINT (b) (4) | 14 Sep 2020 14:10:05 |

US3712094

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:25:14

[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 01:01:24 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 17:59:04 |
| User entered 'Clinic (Clinic)' | (b) (4), (b) (6) | 14 Sep 2020 21:50:45 |

US3712094

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:25:14

[Folder OID](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:24 |
| User entered 'SCRN' | System | 14 Sep 2020 21:50:45 |

US3712094

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:17 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:20:50 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 17:59:34 |
| User entered (b) (6) 1978' | RWS_ENDPOINT ENDPOINT (b) (4) | 14 Sep 2020 14:10:06 |

US3712094

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:25:14

[Age](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:17 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:20:50 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 17:59:34 |
| User entered '41' | (b) (4), (b) (6) | 14 Sep 2020 21:51:07 |

US3712094

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:25:14

[Age Units](#)

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:17 |
| User entered 'YEARS' | System | 14 Sep 2020 21:51:07 |

US3712094

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:25:14

[Age \(Derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:17 |
| User entered '41' | System | 14 Sep 2020 21:51:20 |

US3712094

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:25:14

[Sex](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:17 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:20:50 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 17:59:34 |
| User entered 'Female (F)' | (b) (4), (b) (6) | 14 Sep 2020 21:51:07 |

US3712094

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:25:14

[Ethnicity](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:17 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:20:50 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 17:59:34 |
| User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)' | (b) (4), (b) (6) | 14 Sep 2020 21:51:07 |

US3712094

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:25:14

[White](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:17 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:20:50 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 17:59:34 |
| User entered 'l' | (b) (4), (b) (6) | 14 Sep 2020 21:51:07 |

US3712094

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:25:14

[Black](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:17 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:20:50 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 17:59:34 |
| User entered '0' | (b) (4), (b) (6) | 14 Sep 2020 21:51:07 |

US3712094

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:25:14

[Asian](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:17 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:20:50 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 17:59:34 |
| User entered '0' | (b) (4), (b) (6) | 14 Sep 2020 21:51:07 |

US3712094

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:25:14

[American Indian or Alaska Native](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:17 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:20:50 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 17:59:34 |
| User entered '0' | (b) (4), (b) (6) | 14 Sep 2020 21:51:07 |

US3712094

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:25:14

[Native Hawaiian or other Pacific Islander](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:17 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:20:50 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 17:59:34 |
| User entered '0' | (b) (4), (b) (6) | 14 Sep 2020 21:51:07 |

US3712094

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:25:14

[Other](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:17 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:20:50 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 17:59:34 |
| User entered '0' | (b) (4), (b) (6) | 14 Sep 2020 21:51:07 |

US3712094

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:25:14

[If race is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:17 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:20:50 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 17:59:34 |
| User entered empty. | (b) (4), (b) (6) | 14 Sep 2020 21:51:07 |

US3712094

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:25:14

[Unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:17 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:20:50 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 17:59:34 |
| User entered '0' | (b) (4), (b) (6) | 14 Sep 2020 21:51:07 |

US3712094

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:25:14

[Not reported](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:17 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:20:50 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 17:59:34 |
| User entered '0' | (b) (4), (b) (6) | 14 Sep 2020 21:51:07 |

US3712094

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:25:14

Date of Informed Consent (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:17 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:20:50 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 17:59:44 |
| User entered '14 Sep 2020' | (b) (4), (b) (6) | 14 Sep 2020 21:51:20 |

US3712094

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:17 |
| User entered 'Sep 2020' | System | 14 Sep 2020 21:51:20 |

US3712094

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:17 |
| User entered '2020' | System | 14 Sep 2020 21:51:20 |

US3712094

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:25:14

[Protocol Version](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:17 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:20:50 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 17:59:44 |
| User entered 'Amendment 3 (3)' | (b) (4), (b) (6) | 14 Sep 2020 21:51:20 |

US3712094

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:17 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:20:50 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 17:59:44 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | (b) (4), (b) (6) | 21 Sep 2020 16:39:47 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4), (b) (6) | 15 Sep 2020 11:26:45 |
| Query 'Data is required. Please complete.' answered with 'pending randomization' (Site from System). | (b) (4), (b) (6) | 14 Sep 2020 21:51:22 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 14 Sep 2020 21:51:20 |
| User entered empty. | (b) (4), (b) (6) | 14 Sep 2020 21:51:20 |

US3712094

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:17 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:20:50 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 17:59:44 |
| User entered empty. | (b) (4), (b) (6) | 14 Sep 2020 21:51:20 |

US3712094

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:25:14

If reason for screen fail is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:17 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:20:50 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 17:59:44 |
| User entered empty. | (b) (4), (b) (6) | 14 Sep 2020 21:51:20 |

US3712094

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:25:14

[Was this participant screened previously?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:17 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:20:50 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 17:59:44 |
| User entered 'No (N)' | (b) (4), (b) (6) | 14 Sep 2020 21:51:20 |

US3712094

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:25:14

[If Yes, previous participant number](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:17 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:20:50 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 17:59:44 |
| User entered empty. | RWS_ENDPOINT ENDPOINT (b) (4) | 14 Sep 2020 14:10:05 |

US3712094

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:25:14

[Enrollment Trigger](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:17 |
| User entered 'I' | System | 21 Sep 2020 16:39:53 |

US3712094

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:17 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:03:10 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 21 Sep 2020 16:39:53 |

US3712094

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 09:25:14

[Were any significant conditions reported?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:17 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:03:16 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 22 Sep 2020 16:14:53 |

US3712094

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:25:14

[Condition](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:17 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:04:51 |
| User coded data point as SOC: Gastrointestinal disorders, HLGT: Dental and gingival conditions, HLT: Dental disorders NEC, PT: Tooth impacted, LLT: Impacted wisdom tooth - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 22 Sep 2020 16:15:54 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 22 Sep 2020 16:15:54 |
| Data point term sent to Coder | System | 22 Sep 2020 16:15:20 |
| User entered 'Wisdom teeth impaction' | (b) (4), (b) (6) | 22 Sep 2020 16:15:10 |

US3712094

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:17 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:04:51 |
| User entered 'UN UNK 2000' | (b) (4), (b) (6) | 22 Sep 2020 16:15:10 |

US3712094

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:25:14

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:17 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:04:51 |
| User entered '0' | (b) (4), (b) (6) | 22 Sep 2020 16:15:10 |

US3712094

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:25:14

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:17 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:04:51 |
| User entered 'No (N)' | (b) (4), (b) (6) | 22 Sep 2020 16:15:10 |

US3712094

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:17 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:04:51 |
| User entered 'UN UNK 2000' | (b) (4), (b) (6) | 22 Sep 2020 16:15:10 |

US3712094

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:25:14

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:17 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:04:51 |
| User entered '0' | (b) (4), (b) (6) | 22 Sep 2020 16:15:10 |

US3712094

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:17 |
| User entered 'Jan 2000' | System | 22 Sep 2020 16:15:10 |

US3712094

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:17 |
| User entered '2000' | System | 22 Sep 2020 16:15:10 |

US3712094

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:17 |
| User entered 'Jan 2000' | System | 22 Sep 2020 16:15:10 |

US3712094

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:17 |
| User entered '2000' | System | 22 Sep 2020 16:15:10 |

US3712094

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:25:14

[Condition](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:17 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:04:51 |
| User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Dental and gingival therapeutic procedures, PT: Wisdom teeth removal, LLT: Wisdom teeth removal - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 22 Sep 2020 16:17:43 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 22 Sep 2020 16:17:43 |
| Data point term sent to Coder | System | 22 Sep 2020 16:16:22 |
| User entered 'Wisdom teeth extraction' | (b) (4), (b) (6) | 22 Sep 2020 16:15:43 |

US3712094

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:17 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:04:51 |
| User entered 'UN UNK 2000' | (b) (4), (b) (6) | 22 Sep 2020 16:15:43 |

US3712094

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:25:14

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:17 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:04:51 |
| User entered '0' | (b) (4), (b) (6) | 22 Sep 2020 16:15:43 |

US3712094

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:25:14

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:17 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:04:51 |
| User entered 'No (N)' | (b) (4), (b) (6) | 22 Sep 2020 16:15:43 |

US3712094

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:17 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:04:51 |
| User entered 'UN UNK 2000' | (b) (4), (b) (6) | 22 Sep 2020 16:15:43 |

US3712094

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:25:14

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:17 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:04:51 |
| User entered '0' | (b) (4), (b) (6) | 22 Sep 2020 16:15:43 |

US3712094

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:17 |
| User entered 'Jan 2000' | System | 22 Sep 2020 16:15:43 |

US3712094

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:17 |
| User entered '2000' | System | 22 Sep 2020 16:15:43 |

US3712094

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:17 |
| User entered 'Jan 2000' | System | 22 Sep 2020 16:15:43 |

US3712094

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:17 |
| User entered '2000' | System | 22 Sep 2020 16:15:43 |

US3712094

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:25:14

[Condition](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:17 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:04:51 |
| User coded data point as SOC: Psychiatric disorders, HLGT: Manic and bipolar mood disorders and disturbances, HLT: Bipolar disorders, PT: Bipolar II disorder, LLT: Bipolar II disorder - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 22 Sep 2020 16:17:42 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 22 Sep 2020 16:17:42 |
| Data point term sent to Coder | System | 22 Sep 2020 16:16:22 |
| User entered 'Bipolar Disorder Type II' | (b) (4), (b) (6) | 22 Sep 2020 16:16:07 |

US3712094

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:17 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:04:51 |
| User entered 'UN UNK 2012' | (b) (4), (b) (6) | 22 Sep 2020 16:16:07 |

US3712094

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:25:14

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:17 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:04:51 |
| User entered '0' | (b) (4), (b) (6) | 22 Sep 2020 16:16:07 |

US3712094

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:25:14

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:17 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:04:51 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 22 Sep 2020 16:16:07 |

US3712094

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:17 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:04:51 |
| User entered empty. | (b) (4), (b) (6) | 22 Sep 2020 16:16:07 |

US3712094

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:25:14

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:17 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:04:51 |
| User entered '0' | (b) (4), (b) (6) | 22 Sep 2020 16:16:07 |

US3712094

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:17 |
| User entered 'Jan 2012' | System | 22 Sep 2020 16:16:07 |

US3712094

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:17 |
| User entered '2012' | System | 22 Sep 2020 16:16:07 |

US3712094

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:17 |
| User entered empty. | System | 22 Sep 2020 16:16:07 |

US3712094

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:17 |
| User entered empty. | System | 22 Sep 2020 16:16:07 |

US3712094

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:25:14

Condition

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:17 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:04:51 |
| User coded data point as SOC: Surgical and medical procedures, HLGT: Breast therapeutic procedures, HLT: Breast therapeutic procedures NEC, PT: Mammoplasty, LLT: Breast prosthesis implantation - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 22 Sep 2020 16:18:40 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 22 Sep 2020 16:18:40 |
| Data point term sent to Coder | System | 22 Sep 2020 16:17:23 |
| User entered 'BREAST IMPLANTS' reason for change: Data Entry Error | (b) (4), (b) (6) | 22 Sep 2020 16:17:05 |
| User entered 'Breast Impants' | (b) (4), (b) (6) | 22 Sep 2020 16:16:31 |

US3712094

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:17 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:04:51 |
| User entered 'UN UNK 2007' | (b) (4), (b) (6) | 22 Sep 2020 16:16:31 |

US3712094

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:25:14

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:17 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:04:51 |
| User entered '0' | (b) (4), (b) (6) | 22 Sep 2020 16:16:31 |

US3712094

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:25:14

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:17 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:04:51 |
| User entered 'No (N)' | (b) (4), (b) (6) | 22 Sep 2020 16:16:31 |

US3712094

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:17 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:04:51 |
| User entered 'UN UNK 2007' | (b) (4), (b) (6) | 22 Sep 2020 16:16:31 |

US3712094

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:25:14

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:17 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:04:51 |
| User entered '0' | (b) (4), (b) (6) | 22 Sep 2020 16:16:31 |

US3712094

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:17 |
| User entered 'Jan 2007' | System | 22 Sep 2020 16:16:31 |

US3712094

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:17 |
| User entered '2007' | System | 22 Sep 2020 16:16:31 |

US3712094

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:17 |
| User entered 'Jan 2007' | System | 22 Sep 2020 16:16:31 |

US3712094

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:17 |
| User entered '2007' | System | 22 Sep 2020 16:16:31 |

US3712094

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:25:14

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:24 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:07:25 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 22 Sep 2020 16:12:53 |

US3712094

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:25:14

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:24 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:07:25 |
| User entered '14 Sep 2020' | (b) (4), (b) (6) | 22 Sep 2020 16:12:53 |

US3712094

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:25:14

[Time of assessment \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:24 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:07:25 |
| User entered '10:11' | (b) (4), (b) (6) | 22 Sep 2020 16:12:53 |

US3712094

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:24 |
| User entered '14 Sep 2020 10:11' | System | 22 Sep 2020 16:12:53 |

US3712094

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:24 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:07:25 |
| User entered '169.0' cm | (b) (4), (b) (6) | 22 Sep 2020 16:12:53 |
| DataPoint set to visible. | System | 21 Sep 2020 16:39:53 |

US3712094

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:24 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:07:25 |
| User entered '70.0' kg | (b) (4), (b) (6) | 22 Sep 2020 16:12:53 |
| DataPoint set to visible. | System | 21 Sep 2020 16:39:53 |

US3712094

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:24 |
| User entered '24.50895' | System | 22 Sep 2020 16:12:53 |
| DataPoint set to visible. | System | 21 Sep 2020 16:39:53 |

US3712094

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:25:14

[BMI units](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:24 |
| User entered 'kg/m2' | System | 22 Sep 2020 16:12:53 |
| DataPoint set to visible. | System | 21 Sep 2020 16:39:53 |

US3712094

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:24 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:07:25 |
| User entered '37.3' C | (b) (4), (b) (6) | 22 Sep 2020 16:12:53 |

US3712094

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:25:14

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:24 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:07:25 |
| User entered 'Oral (Oral)' | (b) (4), (b) (6) | 22 Sep 2020 16:12:53 |

US3712094

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:25:14

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:24 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:07:25 |
| User entered empty. | (b) (4), (b) (6) | 22 Sep 2020 16:12:53 |

US3712094

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:25:14

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:24 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:07:25 |
| User entered '66' | (b) (4), (b) (6) | 22 Sep 2020 16:12:53 |

US3712094

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:25:14

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:24 |
| User entered 'bpm' | System | 22 Sep 2020 16:12:53 |

US3712094

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:24 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:07:25 |
| User entered '16' | (b) (4), (b) (6) | 22 Sep 2020 16:12:53 |

US3712094

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:25:14

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:24 |
| User entered 'breaths/min' | System | 22 Sep 2020 16:12:53 |

US3712094

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:24 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:07:25 |
| User entered '114' | (b) (4), (b) (6) | 22 Sep 2020 16:12:53 |

US3712094

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:25:14

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:24 |
| User entered 'mmHg' | System | 22 Sep 2020 16:12:53 |

US3712094

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:24 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:07:25 |
| User entered '75' | (b) (4), (b) (6) | 22 Sep 2020 16:12:53 |

US3712094

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:25:14

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:24 |
| User entered 'mmHg' | System | 22 Sep 2020 16:12:53 |

US3712094

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:25:14

[Height \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:24 |

US3712094

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:25:14

[Weight \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:24 |

US3712094

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:25:14

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:17 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:08:10 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 22 Sep 2020 16:13:02 |

US3712094

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:25:14

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:17 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:08:10 |
| User entered '14 Sep 2020' | (b) (4), (b) (6) | 22 Sep 2020 16:13:02 |

US3712094

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:25:14

Date of assessment (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:17 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:20:50 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:08:27 |
| User entered '14 Sep 2020' | (b) (4), (b) (6) | 22 Sep 2020 16:13:19 |

US3712094

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:17 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:20:50 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:08:27 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 22 Sep 2020 16:13:19 |

US3712094

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:17 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:20:50 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:08:27 |
| User entered empty. | (b) (4), (b) (6) | 22 Sep 2020 16:13:19 |

US3712094

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:17 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:20:50 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:08:27 |
| User entered empty. | (b) (4), (b) (6) | 22 Sep 2020 16:13:19 |

US3712094

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:17 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:20:50 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:08:27 |
| User entered empty. | (b) (4), (b) (6) | 22 Sep 2020 16:13:19 |

US3712094

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:25:14

[Date of surgery unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:17 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:20:50 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:08:27 |
| User entered '0' | (b) (4), (b) (6) | 22 Sep 2020 16:13:19 |

US3712094

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:17 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:20:50 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:08:27 |
| User entered empty. | (b) (4), (b) (6) | 22 Sep 2020 16:13:19 |

US3712094

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:25:14

[Date of last menstruation unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:17 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:20:50 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:08:27 |
| User entered '0' | (b) (4), (b) (6) | 22 Sep 2020 16:13:19 |

US3712094

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:25:14

[Was the pregnancy test performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:24 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:08:35 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 22 Sep 2020 16:13:41 |

US3712094

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:25:14

Date of test (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:24 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:08:35 |
| User entered '14 Sep 2020' | (b) (4), (b) (6) | 22 Sep 2020 16:13:41 |

US3712094

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:25:14

[Test performed](#)

| Audit | User | Time (GMT) |
|------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:24 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:08:35 |
| User entered 'Urine (URINE)' | (b) (4), (b) (6) | 22 Sep 2020 16:13:41 |

US3712094

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:25:14

[Result](#)

| Audit | User | Time (GMT) |
|------------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:24 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:08:35 |
| User entered 'Negative (NEGATIVE)' | (b) (4), (b) (6) | 22 Sep 2020 16:13:41 |

US3712094

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:25:14

[Was FSH sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:24 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:08:35 |
| User entered 'No (N)' | (b) (4), (b) (6) | 22 Sep 2020 16:13:41 |

US3712094

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:25:14

[Collection date](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:24 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:08:35 |
| User entered empty. | (b) (4), (b) (6) | 22 Sep 2020 16:13:41 |

US3712094

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:25:14

[Collection time](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:24 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:08:35 |
| User entered empty. | (b) (4), (b) (6) | 22 Sep 2020 16:13:41 |

US3712094

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:24 |
| User entered empty. | System | 22 Sep 2020 16:13:41 |

US3712094

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:25:14

[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 01:01:24 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:08:56 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 22 Sep 2020 16:14:42 |

US3712094

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:25:14

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 01:01:24 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:08:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 22 Sep 2020 16:14:42 |

US3712094

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:25:14

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 01:01:24 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:08:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 22 Sep 2020 16:14:42 |

US3712094

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:25:14

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 01:01:24 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:08:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 22 Sep 2020 16:14:42 |

US3712094

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:25:14

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 01:01:24 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:08:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 22 Sep 2020 16:14:42 |

US3712094

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:25:14

[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 01:01:24 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:08:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 22 Sep 2020 16:14:42 |

US3712094

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:25:14

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 01:01:24 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:08:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 22 Sep 2020 16:14:42 |

US3712094

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:25:14

[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 01:01:24 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:08:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 22 Sep 2020 16:14:42 |

US3712094

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:25:14

[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 01:01:24 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:08:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 22 Sep 2020 16:14:42 |

US3712094

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:25:14

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 01:01:24 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:08:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 22 Sep 2020 16:14:42 |

US3712094

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:25:14

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 01:01:24 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:08:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 22 Sep 2020 16:14:42 |

US3712094

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:25:14

Other

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:24 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:08:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 22 Sep 2020 16:14:42 |

US3712094

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:25:14

[Specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:24 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:08:56 |
| User entered empty. | (b) (4), (b) (6) | 22 Sep 2020 16:14:42 |

US3712094

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:25:14

No Risk Identified

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:24 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 22 Sep 2020 16:14:42 |

US3712094

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:25:14

Resides in Nursing Home or Assisted Living Facility

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:24 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:08:56 |
| User entered '0' | (b) (4), (b) (6) | 22 Sep 2020 16:14:42 |

US3712094

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:25:14

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 01:01:24 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:08:56 |
| User entered '0' | (b) (4), (b) (6) | 22 Sep 2020 16:14:42 |

US3712094

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:25:14

[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 01:01:24 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:08:56 |
| User entered '0' | (b) (4), (b) (6) | 22 Sep 2020 16:14:42 |

US3712094

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:25:14

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 01:01:24 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:08:56 |
| User entered '0' | (b) (4), (b) (6) | 22 Sep 2020 16:14:42 |

US3712094

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:24 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:08:56 |
| User entered 'I' | (b) (4), (b) (6) | 22 Sep 2020 16:14:42 |

US3712094

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:25:14

Other

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:24 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| User entered 'I' | (b) (4) (b) (4), (b) (6) | 22 Sep 2020 16:14:42 |

US3712094

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:25:14

[Specify](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 01:01:24 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:08:56 |
| User entered 'Lives with people who are at occupational risk of exposure' | (b) (4), (b) (6) | 22 Sep 2020 16:14:42 |

US3712094

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:25:14

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| Data hard unlocked. | (b) (4), (b) (6) | 08 Apr 2021 22:42:43 |
| | | |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:27:43 |
| | | |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 18:09:43 |
| | | |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 21 Sep 2020 16:40:05 |
| | | |

US3712094

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| Data hard unlocked. | (b) (4), (b) (6) | 08 Apr 2021 22:42:43 |
| | | |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:27:43 |
| | | |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 18:09:43 |
| | | |
| User entered '21 Sep 2020' | (b) (4), (b) (6) | 21 Sep 2020 16:40:05 |
| | | |

US3712094

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| Data hard unlocked. | (b) (4), (b) (6) | 08 Apr 2021 22:42:43 |
| | | |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:27:43 |
| | | |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 18:09:43 |
| | | |
| User entered 'Clinic (Clinic)' | (b) (4), (b) (6) | 21 Sep 2020 16:40:05 |
| | | |

US3712094

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:25:14

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| Data hard unlocked. | (b) (4), (b) (6) | 08 Apr 2021 22:42:43 |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:27:43 |
| | | |
| User entered 'VISIT1' | System | 21 Sep 2020 16:40:05 |

US3712094

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| Data hard unlocked. | (b) (4), (b) (6) | 08 Apr 2021 22:42:48 |
| | | |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:27:43 |
| | | |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 18:10:01 |
| | | |
| User entered '21 SEP 2020' | RWS_ENDPOINT ENDPOINT (b) (4) | 21 Sep 2020 15:50:41 |
| | | |

US3712094

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| Data hard unlocked. | (b) (4), (b) (6) | 08 Apr 2021 22:42:48 |
| | | |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:27:43 |
| | | |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 18:10:01 |
| | | |
| User entered '115005' | RWS_ENDPOINT ENDPOINT (b) (4) | 21 Sep 2020 15:50:41 |
| | | |

US3712094

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|---|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| Data hard unlocked. | (b) (4), (b) (6) | 08 Apr 2021 22:42:48 |
| | | |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:27:43 |
| | | |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 18:10:01 |
| | | |
| User entered '>=18 and <65 years and not at risk (1)' | RWS_ENDPOINT ENDPOINT (b) (4) | 21 Sep 2020 15:50:41 |
| | | |

US3712094

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:25:14

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) | 30 Apr 2021 01:58:00 |
| | | |
| Data hard unlocked. | (b) (4), (b) (6) | 08 Apr 2021 22:42:48 |
| | | |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:27:43 |
| | | |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 18:10:01 |
| | | |
| User entered 'No (N)' | (b) (4), (b) (6) | 21 Sep 2020 16:41:24 |
| | | |

US3712094

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:25:14

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) | 30 Apr 2021 01:58:00 |
| | | |
| Data hard unlocked. | (b) (4), (b) (6) | 08 Apr 2021 22:42:48 |
| | | |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:27:43 |
| | | |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 18:10:01 |
| | | |
| User entered 'No (N)' | (b) (4), (b) (6) | 21 Sep 2020 16:41:24 |
| | | |

US3712094

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| Data hard unlocked. | (b) (4), (b) (6) | 08 Apr 2021 22:42:48 |
| | | |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:27:43 |
| | | |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 18:10:01 |
| | | |
| User entered 'No (N)' | (b) (4), (b) (6) | 21 Sep 2020 16:41:24 |
| | | |

US3712094

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:25:14

[Diabetes \(Type I, Type 2, or gestational\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| Data hard unlocked. | (b) (4), (b) (6) | 08 Apr 2021 22:42:48 |
| | | |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:27:43 |
| | | |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 18:10:01 |
| | | |
| User entered 'No (N)' | (b) (4), (b) (6) | 21 Sep 2020 16:41:24 |
| | | |

US3712094

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:25:14

[Liver Disease](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| Data hard unlocked. | (b) (4), (b) (6) | 08 Apr 2021 22:42:48 |
| | | |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:27:43 |
| | | |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 18:10:01 |
| | | |
| User entered 'No (N)' | (b) (4), (b) (6) | 21 Sep 2020 16:41:24 |
| | | |

US3712094

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:25:14

[Human Immunodeficiency Virus \(HIV\) infection](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| Data hard unlocked. | (b) (4), (b) (6) | 08 Apr 2021 22:42:48 |
| | | |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:27:43 |
| | | |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 18:10:01 |
| | | |
| User entered 'No (N)' | (b) (4), (b) (6) | 21 Sep 2020 16:41:24 |
| | | |
| Amendment Manager: DataPoint set to visible. | System | 19 Sep 2020 09:08:45 |

US3712094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:25:14

[Height](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| Data hard unlocked. | (b) (4), (b) (6) | 08 Apr 2021 22:42:52 |
| | | |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:27:43 |
| | | |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 18:10:33 |
| | | |
| User entered '169.0' cm | (b) (4), (b) (6) | 22 Sep 2020 16:26:48 |
| | | |

US3712094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:25:14

[Weight](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| Data hard unlocked. | (b) (4), (b) (6) | 08 Apr 2021 22:42:52 |
| | | |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:27:43 |
| | | |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 18:10:33 |
| | | |
| User entered '70.8' kg | (b) (4), (b) (6) | 22 Sep 2020 16:26:48 |
| | | |

US3712094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:25:14

[Height](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| Data hard unlocked. | (b) (4), (b) (6) | 08 Apr 2021 22:42:52 |
| | | |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:27:43 |
| | | |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 18:10:33 |
| | | |
| User entered '169.0' cm | (b) (4), (b) (6) | 22 Sep 2020 16:26:48 |
| | | |

US3712094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:25:14

[Weight](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| Data hard unlocked. | (b) (4), (b) (6) | 08 Apr 2021 22:42:52 |
| | | |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:27:43 |
| | | |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 18:10:33 |
| | | |
| User entered '70.8' kg | (b) (4), (b) (6) | 22 Sep 2020 16:26:48 |
| | | |

US3712094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:14

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| Data hard unlocked. | (b) (4), (b) (6) | 08 Apr 2021 22:42:52 |
| | | |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:27:43 |
| | | |
| User accepted default value 'Pre-Dose (PREDOSE)' | (b) (4), (b) (6) | 22 Sep 2020 16:26:48 |
| | | |

US3712094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:14

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| Data hard unlocked. | (b) (4), (b) (6) | 08 Apr 2021 22:42:52 |
| | | |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:27:43 |
| | | |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 18:10:33 |
| | | |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 22 Sep 2020 16:26:48 |
| | | |

US3712094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:14

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| Data hard unlocked. | (b) (4), (b) (6) | 08 Apr 2021 22:42:52 |
| | | |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:27:43 |
| | | |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 18:10:33 |
| | | |
| User entered '21 Sep 2020' | (b) (4), (b) (6) | 22 Sep 2020 16:26:48 |
| | | |

US3712094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:14

[Time of assessment \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| Data hard unlocked. | (b) (4), (b) (6) | 08 Apr 2021 22:42:52 |
| | | |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:27:43 |
| | | |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 18:10:33 |
| | | |
| User entered '11:18' | (b) (4), (b) (6) | 22 Sep 2020 16:26:48 |
| | | |

US3712094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| Data hard unlocked. | (b) (4), (b) (6) | 08 Apr 2021 22:42:52 |
| | | |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:27:43 |
| | | |
| User entered '21 Sep 2020 11:18' | System | 22 Sep 2020 16:26:48 |

US3712094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:14

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| Data hard unlocked. | (b) (4), (b) (6) | 08 Apr 2021 22:42:52 |
| | | |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:27:43 |
| | | |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 18:10:33 |
| | | |
| User entered '36.8' C | (b) (4), (b) (6) | 22 Sep 2020 16:26:48 |
| | | |

US3712094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:14

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| Data hard unlocked. | (b) (4), (b) (6) | 08 Apr 2021 22:42:52 |
| | | |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:27:43 |
| | | |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 18:10:33 |
| | | |
| User entered 'Oral (Oral)' | (b) (4), (b) (6) | 22 Sep 2020 16:26:48 |
| | | |

US3712094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:14

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| Data hard unlocked. | (b) (4), (b) (6) | 08 Apr 2021 22:42:52 |
| | | |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:27:43 |
| | | |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 18:10:33 |
| | | |
| User entered empty. | (b) (4), (b) (6) | 22 Sep 2020 16:26:48 |
| | | |

US3712094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:14

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| Data hard unlocked. | (b) (4), (b) (6) | 08 Apr 2021 22:42:52 |
| | | |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:27:43 |
| | | |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 18:10:33 |
| | | |
| User closed query 'Data is required. Please provide.' (Site from System). | System | 22 Sep 2020 16:27:12 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). | | 22 Sep 2020 16:27:12 |
| User entered '67' reason for change: Data Entry Error | (b) (4), (b) (6) | 22 Sep 2020 16:27:12 |
| | | |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 22 Sep 2020 16:26:48 |
| User entered empty. | (b) (4), (b) (6) | 22 Sep 2020 16:26:48 |
| | | |

US3712094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:14

[Pulse units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| Data hard unlocked. | (b) (4), (b) (6) | 08 Apr 2021 22:42:52 |
| | | |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:27:43 |
| | | |
| User entered 'bpm' | System | 22 Sep 2020 16:27:12 |
| User entered empty. | System | 22 Sep 2020 16:26:48 |

US3712094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| Data hard unlocked. | (b) (4), (b) (6) | 08 Apr 2021 22:42:52 |
| | | |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:27:43 |
| | | |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 18:10:33 |
| | | |
| User closed query 'Data is required. Please provide.' (Site from System). | System | 22 Sep 2020 16:27:12 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). | | 22 Sep 2020 16:27:12 |
| User entered '14' reason for change: Data Entry Error | (b) (4), (b) (6) | 22 Sep 2020 16:27:12 |
| | | |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 22 Sep 2020 16:26:48 |
| User entered empty. | (b) (4), (b) (6) | 22 Sep 2020 16:26:48 |
| | | |

US3712094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:14

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| Data hard unlocked. | (b) (4), (b) (6) | 08 Apr 2021 22:42:52 |
| | | |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:27:43 |
| | | |
| User entered 'breaths/min' | System | 22 Sep 2020 16:27:12 |
| User entered empty. | System | 22 Sep 2020 16:26:48 |

US3712094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:14

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| Data hard unlocked. | (b) (4), (b) (6) | 08 Apr 2021 22:42:52 |
| | | |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:27:43 |
| | | |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 18:10:33 |
| | | |
| User closed query 'Data is required. Please provide.' (Site from System). | System | 22 Sep 2020 16:27:12 |
| Query 'Data is required. Please provide.' answered by System | | 22 Sep 2020 16:27:12 |
| data change (Site from System). | | |
| User entered '110' reason for change: Data Entry | (b) (4), (b) (6) | 22 Sep 2020 16:27:12 |
| Error | | |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 22 Sep 2020 16:26:48 |
| User entered empty. | (b) (4), (b) (6) | 22 Sep 2020 16:26:48 |
| | | |

US3712094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:14

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| Data hard unlocked. | (b) (4), (b) (6) | 08 Apr 2021 22:42:52 |
| | | |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:27:43 |
| | | |
| User entered 'mmHg' | System | 22 Sep 2020 16:27:12 |
| User entered empty. | System | 22 Sep 2020 16:26:48 |

US3712094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:14

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| Data hard unlocked. | (b) (4), (b) (6) | 08 Apr 2021 22:42:52 |
| | | |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:27:43 |
| | | |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 18:10:33 |
| | | |
| User closed query 'Data is required. Please provide.' (Site from System). | System | 22 Sep 2020 16:27:12 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). | | 22 Sep 2020 16:27:12 |
| User entered '76' reason for change: Data Entry Error | (b) (4), (b) (6) | 22 Sep 2020 16:27:12 |
| | | |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 22 Sep 2020 16:26:48 |
| User entered empty. | (b) (4), (b) (6) | 22 Sep 2020 16:26:48 |
| | | |

US3712094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:14

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| Data hard unlocked. | (b) (4), (b) (6) | 08 Apr 2021 22:42:52 |
| | | |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:27:43 |
| | | |
| User entered 'mmHg' | System | 22 Sep 2020 16:27:12 |
| User entered empty. | System | 22 Sep 2020 16:26:48 |

US3712094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:25:14

[Height](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| Data hard unlocked. | (b) (4), (b) (6) | 08 Apr 2021 22:42:52 |
| | | |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:27:43 |
| | | |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 18:10:33 |
| | | |
| User entered '169.0' cm | (b) (4), (b) (6) | 22 Sep 2020 16:26:48 |
| | | |

US3712094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:25:14

[Weight](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| Data hard unlocked. | (b) (4), (b) (6) | 08 Apr 2021 22:42:52 |
| | | |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:27:43 |
| | | |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 18:10:33 |
| | | |
| User entered '70.8' kg | (b) (4), (b) (6) | 22 Sep 2020 16:26:48 |
| | | |

US3712094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:14

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| Data hard unlocked. | (b) (4), (b) (6) | 08 Apr 2021 22:42:52 |
| | | |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:27:43 |
| | | |
| User accepted default value 'Post-Dose (POSTDOSE)' | (b) (4), (b) (6) | 22 Sep 2020 16:26:48 |
| | | |

US3712094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:14

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| Data hard unlocked. | (b) (4), (b) (6) | 08 Apr 2021 22:42:52 |
| | | |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:27:43 |
| | | |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 18:10:33 |
| | | |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 22 Sep 2020 16:26:48 |
| | | |

US3712094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:14

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| Data hard unlocked. | (b) (4), (b) (6) | 08 Apr 2021 22:42:52 |
| | | |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:27:43 |
| | | |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 18:10:33 |
| | | |
| User entered '21 Sep 2020' | (b) (4), (b) (6) | 22 Sep 2020 16:26:48 |
| | | |

US3712094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:14

[Time of assessment \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| Data hard unlocked. | (b) (4), (b) (6) | 08 Apr 2021 22:42:52 |
| | | |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:27:43 |
| | | |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 18:10:33 |
| | | |
| User entered '13:00' | (b) (4), (b) (6) | 22 Sep 2020 16:26:48 |
| | | |

US3712094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| Data hard unlocked. | (b) (4), (b) (6) | 08 Apr 2021 22:42:52 |
| | | |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:27:43 |
| | | |
| User entered '21 Sep 2020 13:00' | System | 22 Sep 2020 16:26:48 |

US3712094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:14

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| Data hard unlocked. | (b) (4), (b) (6) | 08 Apr 2021 22:42:52 |
| | | |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:27:43 |
| | | |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 18:10:33 |
| | | |
| User entered '36.5' C | (b) (4), (b) (6) | 22 Sep 2020 16:26:48 |
| | | |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:14

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| Data hard unlocked. | (b) (4), (b) (6) | 08 Apr 2021 22:42:52 |
| | | |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:27:43 |
| | | |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 18:10:33 |
| | | |
| User entered 'Oral (Oral)' | (b) (4), (b) (6) | 22 Sep 2020 16:26:48 |
| | | |

US3712094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:14

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| Data hard unlocked. | (b) (4), (b) (6) | 08 Apr 2021 22:42:52 |
| | | |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:27:43 |
| | | |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 18:10:33 |
| | | |
| User entered empty. | (b) (4), (b) (6) | 22 Sep 2020 16:26:48 |
| | | |

US3712094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:14

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| Data hard unlocked. | (b) (4), (b) (6) | 08 Apr 2021 22:42:52 |
| | | |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:27:43 |
| | | |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 18:10:33 |
| | | |
| User closed query 'Data is required. Please provide.' (Site from System). | System | 22 Sep 2020 16:27:41 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). | | 22 Sep 2020 16:27:41 |
| User entered '59' reason for change: Data Entry Error | (b) (4), (b) (6) | 22 Sep 2020 16:27:41 |
| | | |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 22 Sep 2020 16:26:48 |
| User entered empty. | (b) (4), (b) (6) | 22 Sep 2020 16:26:48 |
| | | |

US3712094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:14

[Pulse units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| Data hard unlocked. | (b) (4), (b) (6) | 08 Apr 2021 22:42:52 |
| | | |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:27:43 |
| | | |
| User entered 'bpm' | System | 22 Sep 2020 16:27:41 |
| User entered empty. | System | 22 Sep 2020 16:26:48 |

US3712094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| Data hard unlocked. | (b) (4), (b) (6) | 08 Apr 2021 22:42:52 |
| | | |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:27:43 |
| | | |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 18:10:33 |
| | | |
| User closed query 'Data is required. Please provide.' (Site from System). | System | 22 Sep 2020 16:27:41 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). | | 22 Sep 2020 16:27:41 |
| User entered '16' reason for change: Data Entry Error | (b) (4), (b) (6) | 22 Sep 2020 16:27:41 |
| | | |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 22 Sep 2020 16:26:48 |
| User entered empty. | (b) (4), (b) (6) | 22 Sep 2020 16:26:48 |
| | | |

US3712094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:14

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| Data hard unlocked. | (b) (4), (b) (6) | 08 Apr 2021 22:42:52 |
| | | |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:27:43 |
| | | |
| User entered 'breaths/min' | System | 22 Sep 2020 16:27:41 |
| User entered empty. | System | 22 Sep 2020 16:26:48 |

US3712094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:14

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| Data hard unlocked. | (b) (4), (b) (6) | 08 Apr 2021 22:42:52 |
| | | |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:27:43 |
| | | |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 18:10:33 |
| | | |
| User closed query 'Data is required. Please provide.' (Site from System). | System | 22 Sep 2020 16:27:41 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). | | 22 Sep 2020 16:27:41 |
| User entered '121' reason for change: Data Entry Error | (b) (4), (b) (6) | 22 Sep 2020 16:27:41 |
| | | |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 22 Sep 2020 16:26:48 |
| User entered empty. | (b) (4), (b) (6) | 22 Sep 2020 16:26:48 |
| | | |

US3712094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:14

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| Data hard unlocked. | (b) (4), (b) (6) | 08 Apr 2021 22:42:52 |
| | | |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:27:43 |
| | | |
| User entered 'mmHg' | System | 22 Sep 2020 16:27:41 |
| User entered empty. | System | 22 Sep 2020 16:26:48 |

US3712094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:14

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| Data hard unlocked. | (b) (4), (b) (6) | 08 Apr 2021 22:42:52 |
| | | |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:27:43 |
| | | |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 18:10:33 |
| | | |
| User closed query 'Data is required. Please provide.' (Site from System). | System | 22 Sep 2020 16:27:41 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). | | 22 Sep 2020 16:27:41 |
| User entered '83' reason for change: Data Entry Error | (b) (4), (b) (6) | 22 Sep 2020 16:27:41 |
| | | |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 22 Sep 2020 16:26:48 |
| User entered empty. | (b) (4), (b) (6) | 22 Sep 2020 16:26:48 |
| | | |

US3712094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:14

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| Data hard unlocked. | (b) (4), (b) (6) | 08 Apr 2021 22:42:52 |
| | | |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:27:43 |
| | | |
| User entered 'mmHg' | System | 22 Sep 2020 16:27:41 |
| User entered empty. | System | 22 Sep 2020 16:26:48 |

US3712094

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:25:14

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| Data hard unlocked. | (b) (4), (b) (6) | 08 Apr 2021 22:42:58 |
| | | |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:27:43 |
| | | |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 18:11:27 |
| | | |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 22 Sep 2020 16:27:52 |
| | | |

US3712094

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:25:14

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| Data hard unlocked. | (b) (4), (b) (6) | 08 Apr 2021 22:42:58 |
| | | |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:27:43 |
| | | |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 18:11:27 |
| | | |
| User entered '21 Sep 2020' | (b) (4), (b) (6) | 22 Sep 2020 16:27:52 |
| | | |

US3712094

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:25:14

[Was the pregnancy test performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| Data hard unlocked. | (b) (4), (b) (6) | 08 Apr 2021 22:43:06 |
| | | |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:27:43 |
| | | |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 18:14:31 |
| | | |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 22 Sep 2020 16:28:18 |
| | | |

US3712094

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:25:14

Date of test (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| Data hard unlocked. | (b) (4), (b) (6) | 08 Apr 2021 22:43:06 |
| | | |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:27:43 |
| | | |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 18:14:31 |
| | | |
| User entered '21 Sep 2020' | (b) (4), (b) (6) | 22 Sep 2020 16:28:18 |
| | | |

US3712094

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:25:14

[Test performed](#)

| Audit | User | Time (GMT) |
|------------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| Data hard unlocked. | (b) (4), (b) (6) | 08 Apr 2021 22:43:06 |
| | | |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:27:43 |
| | | |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 18:14:31 |
| | | |
| User entered 'Urine (URINE)' | (b) (4), (b) (6) | 22 Sep 2020 16:28:18 |
| | | |

US3712094

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:25:14

[Result](#)

| Audit | User | Time (GMT) |
|------------------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| Data hard unlocked. | (b) (4), (b) (6) | 08 Apr 2021 22:43:06 |
| | | |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:27:43 |
| | | |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 18:14:31 |
| | | |
| User entered 'Negative (NEGATIVE)' | (b) (4), (b) (6) | 22 Sep 2020 16:28:18 |
| | | |

US3712094

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:25:14

[Was FSH sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| Data hard unlocked. | (b) (4), (b) (6) | 08 Apr 2021 22:43:06 |
| | | |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:27:43 |
| | | |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 18:14:31 |
| | | |
| User entered 'No (N)' | (b) (4), (b) (6) | 22 Sep 2020 16:28:18 |
| | | |

US3712094

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:25:14

[Collection date](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| Data hard unlocked. | (b) (4), (b) (6) | 08 Apr 2021 22:43:06 |
| | | |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:27:43 |
| | | |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 18:14:31 |
| | | |
| User entered empty. | (b) (4), (b) (6) | 22 Sep 2020 16:28:18 |
| | | |

US3712094

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:25:14

[Collection time](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| Data hard unlocked. | (b) (4), (b) (6) | 08 Apr 2021 22:43:06 |
| | | |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:27:43 |
| | | |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 18:14:31 |
| | | |
| User entered empty. | (b) (4), (b) (6) | 22 Sep 2020 16:28:18 |
| | | |

US3712094

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| Data hard unlocked. | (b) (4), (b) (6) | 08 Apr 2021 22:43:06 |
| | | |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:27:43 |
| | | |
| User entered empty. | System | 22 Sep 2020 16:28:18 |

US3712094

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:25:14

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| Data hard unlocked. | (b) (4), (b) (6) | 08 Apr 2021 22:43:17 |
| | | |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:27:43 |
| | | |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 18:14:56 |
| | | |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 21 Sep 2020 16:41:47 |
| | | |

US3712094

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:25:14

[If No, reason not given](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| Data hard unlocked. | (b) (4), (b) (6) | 08 Apr 2021 22:43:17 |
| | | |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:27:43 |
| | | |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 18:14:56 |
| | | |
| User entered empty. | (b) (4), (b) (6) | 21 Sep 2020 16:41:47 |
| | | |

US3712094

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:25:14

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) | 30 Apr 2021 01:58:00 |
| | | |
| Data hard unlocked. | (b) (4), (b) (6) | 08 Apr 2021 22:43:17 |
| | | |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:27:43 |
| | | |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 18:14:56 |
| | | |
| User entered empty. | (b) (4), (b) (6) | 21 Sep 2020 16:41:47 |
| | | |

US3712094

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:25:14

[What was the study treatment?](#)

| Audit | User | Time (GMT) |
|-------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| Data hard unlocked. | (b) (4), (b) (6) | 08 Apr 2021 22:43:17 |
| | | |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:27:43 |
| | | |
| User entered 'MRNA-1273 OR PLACEBO' | System | 21 Sep 2020 16:41:47 |

US3712094

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:25:14

What was the treatment date? (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| Data hard unlocked. | (b) (4), (b) (6) | 08 Apr 2021 22:43:17 |
| | | |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:27:43 |
| | | |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 18:14:56 |
| | | |
| User entered '21 Sep 2020' | (b) (4), (b) (6) | 21 Sep 2020 16:41:47 |
| | | |

US3712094

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| Data hard unlocked. | (b) (4), (b) (6) | 08 Apr 2021 22:43:17 |
| | | |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:27:43 |
| | | |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 18:14:56 |
| | | |
| User entered '12:25' | (b) (4), (b) (6) | 21 Sep 2020 16:41:47 |
| | | |

US3712094

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| Data hard unlocked. | (b) (4), (b) (6) | 08 Apr 2021 22:43:17 |
| | | |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:27:43 |
| | | |
| User entered '21 Sep 2020 12:25' | System | 21 Sep 2020 16:41:47 |

US3712094

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|------------------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| Data hard unlocked. | (b) (4), (b) (6) | 08 Apr 2021 22:43:17 |
| | | |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:27:43 |
| | | |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 18:14:56 |
| | | |
| User entered 'Left Arm (LEFT ARM)' | (b) (4), (b) (6) | 21 Sep 2020 16:41:47 |
| | | |

US3712094

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| Data hard unlocked. | (b) (4), (b) (6) | 08 Apr 2021 22:43:17 |
| | | |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:27:43 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 18:14:56 |
| | | |
| User entered 'ONCE' | System | 21 Sep 2020 16:41:47 |

US3712094

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:25:14

What was the route of administration for the study treatment?

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| Data hard unlocked. | (b) (4), (b) (6) | 08 Apr 2021 22:43:17 |
| | | |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:27:43 |
| | | |
| User entered 'INTRAMUSCULAR' | System | 21 Sep 2020 16:41:47 |

US3712094

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:25:14

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| Data hard unlocked. | (b) (4), (b) (6) | 08 Apr 2021 22:43:58 |
| | | |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:27:43 |
| | | |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 18:15:02 |
| | | |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 22 Sep 2020 16:29:23 |
| | | |

US3712094

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:25:14

Collection date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| Data hard unlocked. | (b) (4), (b) (6) | 08 Apr 2021 22:43:58 |
| | | |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:27:43 |
| | | |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 18:15:02 |
| | | |
| User entered '21 Sep 2020' | (b) (4), (b) (6) | 22 Sep 2020 16:29:23 |
| | | |

US3712094

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:25:14

[Collection time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| Data hard unlocked. | (b) (4), (b) (6) | 08 Apr 2021 22:43:58 |
| | | |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:27:43 |
| | | |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 18:15:02 |
| | | |
| User entered '11:34' | (b) (4), (b) (6) | 22 Sep 2020 16:29:23 |
| | | |

US3712094

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| Data hard unlocked. | (b) (4), (b) (6) | 08 Apr 2021 22:43:58 |
| | | |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:27:43 |
| | | |
| User entered '21 Sep 2020 11:34' | System | 22 Sep 2020 16:29:23 |

US3712094

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:25:14

Collection date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| Data hard unlocked. | (b) (4), (b) (6) | 08 Apr 2021 22:44:03 |
| | | |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:27:43 |
| | | |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 18:15:08 |
| | | |
| User entered '21 Sep 2020' | (b) (4), (b) (6) | 22 Sep 2020 16:38:05 |
| | | |

US3712094

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:25:14

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| Data hard unlocked. | (b) (4), (b) (6) | 08 Apr 2021 22:44:03 |
| | | |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:27:43 |
| | | |
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | (b) (4), (b) (6) | 22 Sep 2020 16:38:05 |
| | | |

US3712094

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:25:14

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| Data hard unlocked. | (b) (4), (b) (6) | 08 Apr 2021 22:44:03 |
| | | |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:27:43 |
| | | |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 18:15:08 |
| | | |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 22 Sep 2020 16:38:05 |
| | | |

US3712094

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:25:14

[Collection time \(00:00 - 23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| Data hard unlocked. | (b) (4), (b) (6) | 08 Apr 2021 22:44:03 |
| | | |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:27:43 |
| | | |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 18:15:08 |
| | | |
| User entered '11:35' | (b) (4), (b) (6) | 22 Sep 2020 16:38:05 |
| | | |

US3712094

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| Data hard unlocked. | (b) (4), (b) (6) | 08 Apr 2021 22:44:03 |
| | | |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:27:43 |
| | | |
| User entered '21 Sep 2020 11:35' | System | 22 Sep 2020 16:38:05 |

US3712094

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:25:14

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| Data hard unlocked. | (b) (4), (b) (6) | 08 Apr 2021 22:44:03 |
| | | |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:27:43 |
| | | |
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | (b) (4), (b) (6) | 22 Sep 2020 16:38:05 |
| | | |

US3712094

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:25:14

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| Data hard unlocked. | (b) (4), (b) (6) | 08 Apr 2021 22:44:03 |
| | | |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:27:43 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 29 Mar 2021 19:40:15 |
| | | |
| User signature succeeded. | William Smith (b) (4) | 20 Feb 2021 17:12:15 |
| | (b) (4) | |
| DataPoint Un-verified. | (b) (4), (b) (6) | 15 Feb 2021 21:00:26 |
| | | |
| Signature has been broken. | (b) (4), (b) (6) | 15 Feb 2021 21:00:26 |
| | | |
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4), (b) (6) | 15 Feb 2021 21:00:26 |
| | | |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 18:15:08 |
| | | |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 22 Sep 2020 16:38:05 |
| | | |

US3712094

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:25:14

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| Data hard unlocked. | (b) (4), (b) (6) | 08 Apr 2021 22:44:03 |
| | | |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:27:43 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 29 Mar 2021 19:40:15 |
| | | |
| User signature succeeded. | William Smith (b) (4) | 20 Feb 2021 17:12:15 |
| | (b) (4) | |
| DataPoint Un-verified. | (b) (4), (b) (6) | 15 Feb 2021 21:00:26 |
| | | |
| Signature has been broken. | (b) (4), (b) (6) | 15 Feb 2021 21:00:26 |
| | | |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6) | 15 Feb 2021 21:00:26 |
| | | |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 18:15:08 |
| | | |
| User entered '11:35' | (b) (4), (b) (6) | 22 Sep 2020 16:38:05 |
| | | |

US3712094

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| Data hard unlocked. | (b) (4), (b) (6) | 08 Apr 2021 22:44:03 |
| | | |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:27:43 |
| | | |
| User entered empty. | System | 15 Feb 2021 21:00:26 |
| User entered '21 Sep 2020 11:35' | System | 22 Sep 2020 16:38:05 |

US3712094

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:25:14

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| Data hard unlocked. | (b) (4), (b) (6) | 08 Apr 2021 22:44:07 |
| | | |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:27:43 |
| | | |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 18:15:13 |
| | | |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 21 Sep 2020 16:42:22 |
| | | |

US3712094

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:25:14

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| Data hard unlocked. | (b) (4), (b) (6) | 08 Apr 2021 22:44:07 |
| | | |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:27:43 |
| | | |
| User entered '1' | System | 21 Sep 2020 16:42:22 |

US3712094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| Data entry locked. | System | 21 Sep 2020 16:41:47 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 21 Sep 2020 16:41:47 |

US3712094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:25:14

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-21T12:56:33', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '84b8e28f-0989-4728-9381-de56258cc4b6' User entered 'Yes (Y)' | System | 21 Sep 2020 16:56:48 |
| | System | 21 Sep 2020 16:56:48 |

US3712094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:25:14

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-21T12:56:38', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '84b8e28f-0989-4728-9381-de56258cc4b6' User entered '97.7' | System | 21 Sep 2020 16:56:48 |
| | System | 21 Sep 2020 16:56:48 |

US3712094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-21T12:56:41', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '84b8e28f-0989-4728-9381-de56258cc4b6' User entered 'No (N)' | System | 21 Sep 2020 16:56:48 |
| | System | 21 Sep 2020 16:56:48 |

US3712094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:25:14

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-21T12:56:47', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '84b8e28f-0989-4728-9381-de56258cc4b6' User entered '21 Sep 2020 12:56' | System | 21 Sep 2020 16:56:48 |
| | System | 21 Sep 2020 16:56:48 |

US3712094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:25:14

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| User entered '21 Sep 2020 12:45' | System | 21 Sep 2020 16:41:47 |

US3712094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:25:14

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| User entered '21 Sep 2020 15:15' | System | 21 Sep 2020 16:41:47 |

US3712094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| Data entry locked. | System | 21 Sep 2020 16:41:47 |
| User entered 'Day 1, after vaccination (at home)' | System | 21 Sep 2020 16:41:47 |

US3712094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:25:14

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-21T19:19:44', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '12cbdf04-1b47-44aa-9bf7-0d3471dfc67b' User entered 'Yes (Y)' | System | 21 Sep 2020 23:20:18 |
| | System | 21 Sep 2020 23:20:18 |

US3712094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:25:14

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-21T19:20:08', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '12cbdf04-1b47-44aa-9bf7-0d3471dfc67b' User entered '97.7' | System | 21 Sep 2020 23:20:18 |
| | System | 21 Sep 2020 23:20:18 |

US3712094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-21T19:20:11', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '12cbdf04-1b47-44aa-9bf7-0d3471dfc67b' | System | 21 Sep 2020 23:20:18 |
| User entered 'No (N)' | System | 21 Sep 2020 23:20:18 |

US3712094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:25:14

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-21T19:20:15', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '12cbdf04-1b47-44aa-9bf7-0d3471dfc67b' User entered '21 Sep 2020 19:20' | System | 21 Sep 2020 23:20:18 |
| | System | 21 Sep 2020 23:20:18 |

US3712094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:25:14

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| User entered '21 Sep 2020 16:10' | System | 21 Sep 2020 16:41:47 |

US3712094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:25:14

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| User entered '22 Sep 2020 11:59' | System | 21 Sep 2020 16:41:47 |

US3712094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| Data entry locked. | System | 21 Sep 2020 16:41:47 |
| User entered 'Day 2' | System | 21 Sep 2020 16:41:47 |

US3712094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:25:14

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-22T21:26:53', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '62449143-e0a7-4271-baf8-868ccfd67a8c' User entered 'Yes (Y)' | System | 23 Sep 2020 01:27:31 |
| | System | 23 Sep 2020 01:27:31 |

US3712094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:25:14

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-22T21:27:12', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '62449143-e0a7-4271-baf8-868ccfd67a8c' User entered '98.3' | System | 23 Sep 2020 01:27:31 |
| | System | 23 Sep 2020 01:27:31 |

US3712094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-22T21:27:14', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '62449143-e0a7-4271-baf8-868ccfd67a8c' User entered 'No (N)' | System | 23 Sep 2020 01:27:31 |
| | System | 23 Sep 2020 01:27:31 |

US3712094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:25:14

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-22T21:27:19', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '62449143-e0a7-4271-baf8-868ccfd67a8c' User entered '22 Sep 2020 21:27' | System | 23 Sep 2020 01:27:31 |
| | System | 23 Sep 2020 01:27:31 |

US3712094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:25:14

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| User entered '22 Sep 2020 12:00' | System | 21 Sep 2020 16:41:47 |

US3712094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:25:14

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| User entered '23 Sep 2020 11:59' | System | 21 Sep 2020 16:41:47 |

US3712094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| Data entry locked. | System | 21 Sep 2020 16:41:47 |
| User entered 'Day 3' | System | 21 Sep 2020 16:41:47 |

US3712094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:25:14

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-23T12:03:19', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '407a1586-ff68-4500-ade6-90c1b9d694ad' User entered 'Yes (Y)' | System | 23 Sep 2020 16:04:48 |
| | System | 23 Sep 2020 16:04:48 |

US3712094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:25:14

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-23T12:03:26', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '407a1586-ff68-4500-ade6-90c1b9d694ad' User entered '98.2' | System | 23 Sep 2020 16:04:48 |
| | System | 23 Sep 2020 16:04:48 |

US3712094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-23T12:03:30', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '407a1586-ff68-4500-ade6-90c1b9d694ad' User entered 'No (N)' | System | 23 Sep 2020 16:04:48 |
| | System | 23 Sep 2020 16:04:48 |

US3712094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:25:14

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-23T12:03:36', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '407a1586-ff68-4500-ade6-90c1b9d694ad' User entered '23 Sep 2020 12:03' | System | 23 Sep 2020 16:04:48 |
| | System | 23 Sep 2020 16:04:48 |

US3712094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:25:14

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| User entered '23 Sep 2020 12:00' | System | 21 Sep 2020 16:41:47 |

US3712094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:25:14

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| User entered '24 Sep 2020 11:59' | System | 21 Sep 2020 16:41:47 |

US3712094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| Data entry locked. | System | 21 Sep 2020 16:41:47 |
| User entered 'Day 4' | System | 21 Sep 2020 16:41:47 |

US3712094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:25:14

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-24T12:00:21', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '75a4a7a5-ace7-4543-9b76-69b35845645d' User entered 'Yes (Y)' | System | 24 Sep 2020 16:00:52 |
| | System | 24 Sep 2020 16:00:52 |

US3712094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:25:14

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-24T12:00:28', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '75a4a7a5-ace7-4543-9b76-69b35845645d' User entered '98.1' | System | 24 Sep 2020 16:00:52 |
| | System | 24 Sep 2020 16:00:52 |

US3712094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-24T12:00:31', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '75a4a7a5-ace7-4543-9b76-69b35845645d' User entered 'No (N)' | System | 24 Sep 2020 16:00:52 |
| | System | 24 Sep 2020 16:00:52 |

US3712094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:25:14

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-24T12:00:35', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '75a4a7a5-ace7-4543-9b76-69b35845645d' User entered '24 Sep 2020 12:00' | System | 24 Sep 2020 16:00:52 |
| | System | 24 Sep 2020 16:00:52 |

US3712094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:25:14

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| User entered '24 Sep 2020 12:00' | System | 21 Sep 2020 16:41:47 |

US3712094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:25:14

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| User entered '25 Sep 2020 11:59' | System | 21 Sep 2020 16:41:47 |

US3712094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| Data entry locked. | System | 21 Sep 2020 16:41:47 |
| User entered 'Day 5' | System | 21 Sep 2020 16:41:47 |

US3712094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:25:14

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-25T16:06:40', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '9fe583b1-ea5f-47f4-b4d6-f22d901e5259' User entered 'Yes (Y)' | System | 25 Sep 2020 20:06:54 |
| | System | 25 Sep 2020 20:06:54 |

US3712094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:25:14

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-25T16:06:44', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '9fe583b1-ea5f-47f4-b4d6-f22d901e5259' User entered '97.9' | System | 25 Sep 2020 20:06:54 |
| | System | 25 Sep 2020 20:06:54 |

US3712094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-25T16:06:47', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '9fe583b1-ea5f-47f4-b4d6-f22d901e5259' | System | 25 Sep 2020 20:06:54 |
| User entered 'No (N)' | System | 25 Sep 2020 20:06:54 |

US3712094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:25:14

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-25T16:06:50', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '9fe583b1-ea5f-47f4-b4d6-f22d901e5259' User entered '25 Sep 2020 16:06' | System | 25 Sep 2020 20:06:54 |
| | System | 25 Sep 2020 20:06:54 |

US3712094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:25:14

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| User entered '25 Sep 2020 12:00' | System | 21 Sep 2020 16:41:47 |

US3712094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:25:14

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| User entered '26 Sep 2020 11:59' | System | 21 Sep 2020 16:41:47 |

US3712094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| Data entry locked. | System | 21 Sep 2020 16:41:47 |
| User entered 'Day 6' | System | 21 Sep 2020 16:41:47 |

US3712094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:25:14

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-26T18:56:13', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '2a688ec9-5154-458c-8311-b15bb57d7774' User entered 'Yes (Y)' | System | 26 Sep 2020 22:56:29 |
| | System | 26 Sep 2020 22:56:29 |

US3712094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:25:14

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-26T18:56:17', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '2a688ec9-5154-458c-8311-b15bb57d7774' User entered '97.4' | System | 26 Sep 2020 22:56:29 |
| | System | 26 Sep 2020 22:56:29 |

US3712094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-26T18:56:22', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '2a688ec9-5154-458c-8311-b15bb57d7774' | System | 26 Sep 2020 22:56:29 |
| User entered 'No (N)' | System | 26 Sep 2020 22:56:29 |

US3712094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:25:14

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-26T18:56:26', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '2a688ec9-5154-458c-8311-b15bb57d7774' User entered '26 Sep 2020 18:56' | System | 26 Sep 2020 22:56:29 |
| | System | 26 Sep 2020 22:56:29 |

US3712094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:25:14

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| User entered '26 Sep 2020 12:00' | System | 21 Sep 2020 16:41:47 |

US3712094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:25:14

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| User entered '27 Sep 2020 11:59' | System | 21 Sep 2020 16:41:47 |

US3712094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| Data entry locked. | System | 21 Sep 2020 16:41:47 |
| User entered 'Day 7' | System | 21 Sep 2020 16:41:47 |

US3712094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:25:14

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-27T16:47:50', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'b948326b-5514-4df5-8360-757f3496f6ec' User entered 'Yes (Y)' | System | 27 Sep 2020 20:48:18 |
| | System | 27 Sep 2020 20:48:18 |

US3712094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:25:14

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-27T16:48:04', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'b948326b-5514-4df5-8360-757f3496f6ec' User entered '97.6' | System | 27 Sep 2020 20:48:18 |
| | System | 27 Sep 2020 20:48:18 |

US3712094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-27T16:48:06', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'b948326b-5514-4df5-8360-757f3496f6ec' | System | 27 Sep 2020 20:48:18 |
| User entered 'No (N)' | System | 27 Sep 2020 20:48:18 |

US3712094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:25:14

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-27T16:48:15', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'b948326b-5514-4df5-8360-757f3496f6ec' User entered '27 Sep 2020 16:48' | System | 27 Sep 2020 20:48:18 |
| | System | 27 Sep 2020 20:48:18 |

US3712094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:25:14

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| User entered '27 Sep 2020 12:00' | System | 21 Sep 2020 16:41:47 |

US3712094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:25:14

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| User entered '28 Sep 2020 11:59' | System | 21 Sep 2020 16:41:47 |

US3712094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| Data entry locked. | System | 21 Sep 2020 16:41:47 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 21 Sep 2020 16:41:47 |

US3712094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:25:14

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-21T12:57:08', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'c642fb93-12d9-451d-a9da-33e635211660' User entered 'None (1)' | System | 21 Sep 2020 16:57:24 |
| | System | 21 Sep 2020 16:57:24 |

US3712094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:25:14

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-21T12:57:11', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'c642fb93-12d9-451d-a9da-33e635211660' User entered 'No (N)' | System | 21 Sep 2020 16:57:24 |
| | System | 21 Sep 2020 16:57:24 |

US3712094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-21T12:57:14', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'c642fb93-12d9-451d-a9da-33e635211660' User entered 'No (N)' | System | 21 Sep 2020 16:57:24 |
| | System | 21 Sep 2020 16:57:24 |

US3712094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:25:14

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-21T12:57:17', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'c642fb93-12d9-451d-a9da-33e635211660' User entered 'None (1)' | System | 21 Sep 2020 16:57:24 |
| | System | 21 Sep 2020 16:57:24 |

US3712094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:25:14

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-21T12:57:22', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'c642fb93-12d9-451d-a9da-33e635211660' User entered '21 Sep 2020 12:57' | System | 21 Sep 2020 16:57:24 |
| | System | 21 Sep 2020 16:57:24 |

US3712094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:25:14

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| User entered '21 Sep 2020 12:45' | System | 21 Sep 2020 16:41:47 |

US3712094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:25:14

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| User entered '21 Sep 2020 15:15' | System | 21 Sep 2020 16:41:47 |

US3712094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| Data entry locked. | System | 21 Sep 2020 16:41:47 |
| User entered 'Day 1, after vaccination (at home)' | System | 21 Sep 2020 16:41:47 |

US3712094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:25:14

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-21T19:20:27', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '79e37424-7154-4a1a-a5f6-5aac6d577a47' | System | 21 Sep 2020 23:20:46 |
| User entered 'None (1)' | System | 21 Sep 2020 23:20:46 |

US3712094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:25:14

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-21T19:20:25', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '79e37424-7154-4a1a-a5f6-5aac6d577a47' User entered 'No (N)' | System | 21 Sep 2020 23:20:46 |
| | System | 21 Sep 2020 23:20:46 |

US3712094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-21T19:20:32', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '79e37424-7154-4a1a-a5f6-5aac6d577a47' User entered 'No (N)' | System | 21 Sep 2020 23:20:46 |
| | System | 21 Sep 2020 23:20:46 |

US3712094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:25:14

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-21T19:20:37', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '79e37424-7154-4a1a-a5f6-5aac6d577a47' | System | 21 Sep 2020 23:20:46 |
| User entered 'None (1)' | System | 21 Sep 2020 23:20:46 |

US3712094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:25:14

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-21T19:20:44', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '79e37424-7154-4a1a-a5f6-5aac6d577a47' | System | 21 Sep 2020 23:20:46 |
| User entered '21 Sep 2020 19:20' | System | 21 Sep 2020 23:20:46 |

US3712094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:25:14

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| User entered '21 Sep 2020 16:10' | System | 21 Sep 2020 16:41:47 |

US3712094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:25:14

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| User entered '22 Sep 2020 11:59' | System | 21 Sep 2020 16:41:47 |

US3712094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| Data entry locked. | System | 21 Sep 2020 16:41:47 |
| User entered 'Day 2' | System | 21 Sep 2020 16:41:47 |

US3712094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:25:14

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-22T21:27:23', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'c5d8a9e3-0978-42f0-80b0-01b4b70f893b' User entered 'None (1)' | System | 23 Sep 2020 01:27:45 |
| | System | 23 Sep 2020 01:27:45 |

US3712094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:25:14

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-22T21:27:33', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'c5d8a9e3-0978-42f0-80b0-01b4b70f893b' User entered 'No (N)' | System | 23 Sep 2020 01:27:45 |
| | System | 23 Sep 2020 01:27:45 |

US3712094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-22T21:27:35', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'c5d8a9e3-0978-42f0-80b0-01b4b70f893b' User entered 'No (N)' | System | 23 Sep 2020 01:27:45 |
| | System | 23 Sep 2020 01:27:45 |

US3712094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:25:14

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-22T21:27:37', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'c5d8a9e3-0978-42f0-80b0-01b4b70f893b' User entered 'None (1)' | System | 23 Sep 2020 01:27:45 |
| | System | 23 Sep 2020 01:27:45 |

US3712094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:25:14

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-22T21:27:41', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'c5d8a9e3-0978-42f0-80b0-01b4b70f893b' User entered '22 Sep 2020 21:27' | System | 23 Sep 2020 01:27:45 |
| | System | 23 Sep 2020 01:27:45 |

US3712094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:25:14

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| User entered '22 Sep 2020 12:00' | System | 21 Sep 2020 16:41:47 |

US3712094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:25:14

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| User entered '23 Sep 2020 11:59' | System | 21 Sep 2020 16:41:47 |

US3712094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| Data entry locked. | System | 21 Sep 2020 16:41:47 |
| User entered 'Day 3' | System | 21 Sep 2020 16:41:47 |

US3712094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:25:14

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-23T12:03:42', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '2c235a05-a84f-4075-956f-d05ce6e11dc7' User entered 'None (1)' | System | 23 Sep 2020 16:04:58 |
| | System | 23 Sep 2020 16:04:58 |

US3712094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:25:14

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-23T12:03:45', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '2c235a05-a84f-4075-956f-d05ce6e11dc7' User entered 'No (N)' | System | 23 Sep 2020 16:04:58 |
| | System | 23 Sep 2020 16:04:58 |

US3712094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-23T12:03:48', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '2c235a05-a84f-4075-956f-d05ce6e11dc7' User entered 'No (N)' | System | 23 Sep 2020 16:04:58 |
| | System | 23 Sep 2020 16:04:58 |

US3712094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:25:14

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-23T12:03:52', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '2c235a05-a84f-4075-956f-d05ce6e11dc7' User entered 'None (1)' | System | 23 Sep 2020 16:04:58 |
| | System | 23 Sep 2020 16:04:58 |

US3712094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:25:14

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-23T12:03:56', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '2c235a05-a84f-4075-956f-d05ce6e11dc7' User entered '23 Sep 2020 12:03' | System | 23 Sep 2020 16:04:58 |
| | System | 23 Sep 2020 16:04:58 |

US3712094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:25:14

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| User entered '23 Sep 2020 12:00' | System | 21 Sep 2020 16:41:47 |

US3712094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:25:14

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| User entered '24 Sep 2020 11:59' | System | 21 Sep 2020 16:41:47 |

US3712094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| Data entry locked. | System | 21 Sep 2020 16:41:47 |
| User entered 'Day 4' | System | 21 Sep 2020 16:41:47 |

US3712094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:25:14

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-24T12:00:39', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'd5e87236-4657-4d89-87e9-c9d98b0cc5cd' User entered 'None (1)' | System | 24 Sep 2020 16:01:25 |
| | System | 24 Sep 2020 16:01:25 |

US3712094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:25:14

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-24T12:00:42', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'd5e87236-4657-4d89-87e9-c9d98b0cc5cd' User entered 'No (N)' | System | 24 Sep 2020 16:01:25 |
| | System | 24 Sep 2020 16:01:25 |

US3712094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-24T12:00:44', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'd5e87236-4657-4d89-87e9-c9d98b0cc5cd' User entered 'No (N)' | System | 24 Sep 2020 16:01:25 |
| | System | 24 Sep 2020 16:01:25 |

US3712094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:25:14

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-24T12:00:47', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'd5e87236-4657-4d89-87e9-c9d98b0cc5cd' User entered 'None (1)' | System | 24 Sep 2020 16:01:25 |
| | System | 24 Sep 2020 16:01:25 |

US3712094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:25:14

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-24T12:00:51', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'd5e87236-4657-4d89-87e9-c9d98b0cc5cd' User entered '24 Sep 2020 12:00' | System | 24 Sep 2020 16:01:25 |
| | System | 24 Sep 2020 16:01:25 |

US3712094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:25:14

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| User entered '24 Sep 2020 12:00' | System | 21 Sep 2020 16:41:47 |

US3712094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:25:14

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| User entered '25 Sep 2020 11:59' | System | 21 Sep 2020 16:41:47 |

US3712094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| Data entry locked. | System | 21 Sep 2020 16:41:47 |
| User entered 'Day 5' | System | 21 Sep 2020 16:41:47 |

US3712094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:25:14

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-25T16:06:54', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '472245ce-c0da-47f8-8b14-3c6dc8b6e143' User entered 'None (1)' | System | 25 Sep 2020 20:07:12 |
| | System | 25 Sep 2020 20:07:12 |

US3712094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-25T16:06:57', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '472245ce-c0da-47f8-8b14-3c6dc8b6e143' User entered 'No (N)' | System | 25 Sep 2020 20:07:12 |
| | System | 25 Sep 2020 20:07:12 |

US3712094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-25T16:06:59', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '472245ce-c0da-47f8-8b14-3c6dc8b6e143' User entered 'No (N)' | System | 25 Sep 2020 20:07:12 |
| | System | 25 Sep 2020 20:07:12 |

US3712094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:25:14

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-25T16:07:01', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '472245ce-c0da-47f8-8b14-3c6dc8b6e143' User entered 'None (1)' | System | 25 Sep 2020 20:07:12 |
| | System | 25 Sep 2020 20:07:12 |

US3712094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:25:14

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-25T16:07:04', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '472245ce-c0da-47f8-8b14-3c6dc8b6e143' User entered '25 Sep 2020 16:07' | System | 25 Sep 2020 20:07:12 |
| | System | 25 Sep 2020 20:07:12 |

US3712094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:25:14

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| User entered '25 Sep 2020 12:00' | System | 21 Sep 2020 16:41:47 |

US3712094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:25:14

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| User entered '26 Sep 2020 11:59' | System | 21 Sep 2020 16:41:47 |

US3712094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| Data entry locked. | System | 21 Sep 2020 16:41:47 |
| User entered 'Day 6' | System | 21 Sep 2020 16:41:47 |

US3712094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:25:14

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-26T18:56:35', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '43bd3bf5-53fc-456b-8843-b9d7e92bfc6d' User entered 'None (1)' | System | 26 Sep 2020 22:56:50 |
| | System | 26 Sep 2020 22:56:50 |

US3712094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:25:14

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-26T18:56:37', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '43bd3bf5-53fc-456b-8843-b9d7e92bfc6d' User entered 'No (N)' | System | 26 Sep 2020 22:56:50 |
| | System | 26 Sep 2020 22:56:50 |

US3712094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-26T18:56:39', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '43bd3bf5-53fc-456b-8843-b9d7e92bfc6d' User entered 'No (N)' | System | 26 Sep 2020 22:56:50 |
| | System | 26 Sep 2020 22:56:50 |

US3712094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:25:14

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-26T18:56:43', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '43bd3bf5-53fc-456b-8843-b9d7e92bfc6d' | System | 26 Sep 2020 22:56:50 |
| User entered 'None (1)' | System | 26 Sep 2020 22:56:50 |

US3712094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:25:14

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-26T18:56:46', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '43bd3bf5-53fc-456b-8843-b9d7e92bfc6d' User entered '26 Sep 2020 18:56' | System | 26 Sep 2020 22:56:50 |
| | System | 26 Sep 2020 22:56:50 |

US3712094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:25:14

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| User entered '26 Sep 2020 12:00' | System | 21 Sep 2020 16:41:47 |

US3712094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:25:14

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| User entered '27 Sep 2020 11:59' | System | 21 Sep 2020 16:41:47 |

US3712094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| Data entry locked. | System | 21 Sep 2020 16:41:47 |
| User entered 'Day 7' | System | 21 Sep 2020 16:41:47 |

US3712094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:25:14

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-27T16:48:25', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'e62dcce9-5baf-427c-8e95-d19d91b6b2b9' User entered 'None (1)' | System | 27 Sep 2020 20:48:42 |
| | System | 27 Sep 2020 20:48:42 |

US3712094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-27T16:48:27', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'e62dcce9-5baf-427c-8e95-d19d91b6b2b9' User entered 'No (N)' | System | 27 Sep 2020 20:48:42 |
| | System | 27 Sep 2020 20:48:42 |

US3712094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-27T16:48:31', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'e62dcce9-5baf-427c-8e95-d19d91b6b2b9' User entered 'No (N)' | System | 27 Sep 2020 20:48:42 |
| | System | 27 Sep 2020 20:48:42 |

US3712094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:25:14

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-27T16:48:33', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'e62dcce9-5baf-427c-8e95-d19d91b6b2b9' User entered 'None (1)' | System | 27 Sep 2020 20:48:42 |
| | System | 27 Sep 2020 20:48:42 |

US3712094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:25:14

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-27T16:48:41', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'e62dcce9-5baf-427c-8e95-d19d91b6b2b9' User entered '27 Sep 2020 16:48' | System | 27 Sep 2020 20:48:42 |
| | System | 27 Sep 2020 20:48:42 |

US3712094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:25:14

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| User entered '27 Sep 2020 12:00' | System | 21 Sep 2020 16:41:47 |

US3712094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:25:14

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| User entered '28 Sep 2020 11:59' | System | 21 Sep 2020 16:41:47 |

US3712094

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| Data entry locked. | System | 21 Sep 2020 16:41:47 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 21 Sep 2020 16:41:47 |

US3712094

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:25:14

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-21T12:57:29', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '0cdd1bb6-86dc-4ea4-bd85-ee4bf660e864' User entered 'None (0)' | System | 21 Sep 2020 16:57:50 |
| | System | 21 Sep 2020 16:57:50 |

US3712094

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:25:14

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-21T12:57:31', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '0cdd1bb6-86dc-4ea4-bd85-ee4bf660e864' User entered 'None (0)' | System | 21 Sep 2020 16:57:50 |
| | System | 21 Sep 2020 16:57:50 |

US3712094

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:25:14

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-21T12:57:34', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '0cdd1bb6-86dc-4ea4-bd85-ee4bf660e864' User entered 'None (0)' | System | 21 Sep 2020 16:57:50 |
| | System | 21 Sep 2020 16:57:50 |

US3712094

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:25:14

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-21T12:57:36', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '0cdd1bb6-86dc-4ea4-bd85-ee4bf660e864' User entered 'None (0)' | System | 21 Sep 2020 16:57:50 |
| | System | 21 Sep 2020 16:57:50 |

US3712094

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:25:14

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-21T12:57:37', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '0cdd1bb6-86dc-4ea4-bd85-ee4bf660e864' User entered 'None (0)' | System | 21 Sep 2020 16:57:50 |
| | System | 21 Sep 2020 16:57:50 |

US3712094

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:25:14

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-21T12:57:39', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '0cdd1bb6-86dc-4ea4-bd85-ee4bf660e864' User entered 'None (0)' | System | 21 Sep 2020 16:57:50 |
| | System | 21 Sep 2020 16:57:50 |

US3712094

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:25:14

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) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-21T12:57:42', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '0cdd1bb6-86dc-4ea4-bd85-ee4bf660e864' User entered 'No (N)' | System | 21 Sep 2020 16:57:50 |
| | System | 21 Sep 2020 16:57:50 |

US3712094

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:25:14

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-21T12:57:47', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '0cdd1bb6-86dc-4ea4-bd85-ee4bf660e864' User entered '21 Sep 2020 12:57' | System | 21 Sep 2020 16:57:50 |
| | System | 21 Sep 2020 16:57:50 |

US3712094

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:25:14

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| User entered '21 Sep 2020 12:45' | System | 21 Sep 2020 16:41:47 |

US3712094

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:25:14

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| User entered '21 Sep 2020 15:15' | System | 21 Sep 2020 16:41:47 |

US3712094

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| Data entry locked. | System | 21 Sep 2020 16:41:47 |
| User entered 'Day 1, after vaccination (at home)' | System | 21 Sep 2020 16:41:47 |

US3712094

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:25:14

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-21T19:20:50', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '15a36850-07d0-43e7-b557-9c3aea6ee011' User entered 'None (0)' | System | 21 Sep 2020 23:21:38 |
| | System | 21 Sep 2020 23:21:38 |

US3712094

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:25:14

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-21T19:20:52', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '15a36850-07d0-43e7-b557-9c3aea6ee011' User entered 'None (0)' | System | 21 Sep 2020 23:21:38 |
| | System | 21 Sep 2020 23:21:38 |

US3712094

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:25:14

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-21T19:20:55', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '15a36850-07d0-43e7-b557-9c3aea6ee011' User entered 'None (0)' | System | 21 Sep 2020 23:21:38 |
| | System | 21 Sep 2020 23:21:38 |

US3712094

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:25:14

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-21T19:20:57', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '15a36850-07d0-43e7-b557-9c3aea6ee011' User entered 'None (0)' | System | 21 Sep 2020 23:21:38 |
| | System | 21 Sep 2020 23:21:38 |

US3712094

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:25:14

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-21T19:21:01', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '15a36850-07d0-43e7-b557-9c3aea6ee011' User entered 'None (0)' | System | 21 Sep 2020 23:21:38 |
| | System | 21 Sep 2020 23:21:38 |

US3712094

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:25:14

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-21T19:21:10', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '15a36850-07d0-43e7-b557-9c3aea6ee011' User entered 'None (0)' | System | 21 Sep 2020 23:21:38 |
| | System | 21 Sep 2020 23:21:38 |

US3712094

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:25:14

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) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-21T19:21:14', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '15a36850-07d0-43e7-b557-9c3aea6ee011' User entered 'No (N)' | System | 21 Sep 2020 23:21:38 |
| | System | 21 Sep 2020 23:21:38 |

US3712094

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:25:14

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-21T19:21:34', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '15a36850-07d0-43e7-b557-9c3aea6ee011' User entered '21 Sep 2020 19:21' | System | 21 Sep 2020 23:21:38 |
| | System | 21 Sep 2020 23:21:38 |

US3712094

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:25:14

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| User entered '21 Sep 2020 16:10' | System | 21 Sep 2020 16:41:47 |

US3712094

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:25:14

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| User entered '22 Sep 2020 11:59' | System | 21 Sep 2020 16:41:47 |

US3712094

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| Data entry locked. | System | 21 Sep 2020 16:41:47 |
| User entered 'Day 2' | System | 21 Sep 2020 16:41:47 |

US3712094

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:25:14

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-22T21:27:45', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '01ef05a7-0096-475f-bf32-c5769c3fa512' User entered 'None (0)' | System | 23 Sep 2020 01:28:03 |
| | System | 23 Sep 2020 01:28:03 |

US3712094

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:25:14

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-22T21:27:46', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '01ef05a7-0096-475f-bf32-c5769c3fa512' User entered 'None (0)' | System | 23 Sep 2020 01:28:03 |
| | System | 23 Sep 2020 01:28:03 |

US3712094

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:25:14

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-22T21:27:48', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '01ef05a7-0096-475f-bf32-c5769c3fa512' User entered 'None (0)' | System | 23 Sep 2020 01:28:03 |
| | System | 23 Sep 2020 01:28:03 |

US3712094

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:25:14

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-22T21:27:50', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '01ef05a7-0096-475f-bf32-c5769c3fa512' User entered 'None (0)' | System | 23 Sep 2020 01:28:03 |
| | System | 23 Sep 2020 01:28:03 |

US3712094

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:25:14

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-22T21:27:51', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '01ef05a7-0096-475f-bf32-c5769c3fa512' User entered 'None (0)' | System | 23 Sep 2020 01:28:03 |
| | System | 23 Sep 2020 01:28:03 |

US3712094

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:25:14

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-22T21:27:53', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '01ef05a7-0096-475f-bf32-c5769c3fa512' User entered 'None (0)' | System | 23 Sep 2020 01:28:03 |
| | System | 23 Sep 2020 01:28:03 |

US3712094

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:25:14

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) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-22T21:27:55', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '01ef05a7-0096-475f-bf32-c5769c3fa512' | System | 23 Sep 2020 01:28:03 |
| User entered 'No (N)' | System | 23 Sep 2020 01:28:03 |

US3712094

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:25:14

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-22T21:27:59', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '01ef05a7-0096-475f-bf32-c5769c3fa512' User entered '22 Sep 2020 21:27' | System | 23 Sep 2020 01:28:03 |
| | System | 23 Sep 2020 01:28:03 |

US3712094

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:25:14

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| User entered '22 Sep 2020 12:00' | System | 21 Sep 2020 16:41:47 |

US3712094

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:25:14

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| User entered '23 Sep 2020 11:59' | System | 21 Sep 2020 16:41:47 |

US3712094

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| Data entry locked. | System | 21 Sep 2020 16:41:47 |
| User entered 'Day 3' | System | 21 Sep 2020 16:41:47 |

US3712094

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:25:14

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-23T12:04:00', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'fcb57cf7-2ee5-42c5-be23-9d683d5ff65c' User entered 'None (0)' | System | 23 Sep 2020 16:05:28 |
| | System | 23 Sep 2020 16:05:28 |

US3712094

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:25:14

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-23T12:04:03', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'fcb57cf7-2ee5-42c5-be23-9d683d5ff65c' User entered 'None (0)' | System | 23 Sep 2020 16:05:28 |
| | System | 23 Sep 2020 16:05:28 |

US3712094

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:25:14

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-23T12:04:10', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'fcb57cf7-2ee5-42c5-be23-9d683d5ff65c' User entered 'None (0)' | System | 23 Sep 2020 16:05:28 |
| | System | 23 Sep 2020 16:05:28 |

US3712094

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:25:14

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-23T12:04:15', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'fcb57cf7-2ee5-42c5-be23-9d683d5ff65c' User entered 'None (0)' | System | 23 Sep 2020 16:05:28 |
| | System | 23 Sep 2020 16:05:28 |

US3712094

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:25:14

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-23T12:04:22', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'fcb57cf7-2ee5-42c5-be23-9d683d5ff65c' User entered 'None (0)' | System | 23 Sep 2020 16:05:28 |
| | System | 23 Sep 2020 16:05:28 |

US3712094

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:25:14

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-23T12:04:24', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'fcb57cf7-2ee5-42c5-be23-9d683d5ff65c' User entered 'None (0)' | System | 23 Sep 2020 16:05:28 |
| | System | 23 Sep 2020 16:05:28 |

US3712094

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:25:14

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) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-23T12:04:27', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'fcb57cf7-2ee5-42c5-be23-9d683d5ff65c' User entered 'No (N)' | System | 23 Sep 2020 16:05:28 |
| | System | 23 Sep 2020 16:05:28 |

US3712094

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:25:14

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-23T12:04:30', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'fcb57cf7-2ee5-42c5-be23-9d683d5ff65c' User entered '23 Sep 2020 12:04' | System | 23 Sep 2020 16:05:28 |
| | System | 23 Sep 2020 16:05:28 |

US3712094

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:25:14

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| User entered '23 Sep 2020 12:00' | System | 21 Sep 2020 16:41:47 |

US3712094

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:25:14

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| User entered '24 Sep 2020 11:59' | System | 21 Sep 2020 16:41:47 |

US3712094

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| Data entry locked. | System | 21 Sep 2020 16:41:47 |
| User entered 'Day 4' | System | 21 Sep 2020 16:41:47 |

US3712094

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:25:14

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-24T12:00:55', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'f838aa6c-a280-4435-9a0b-66fca853aacb' User entered 'None (0)' | System | 24 Sep 2020 16:02:09 |
| | System | 24 Sep 2020 16:02:09 |

US3712094

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:25:14

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-24T12:00:57', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'f838aa6c-a280-4435-9a0b-66fca853aacb' User entered 'None (0)' | System | 24 Sep 2020 16:02:09 |
| | System | 24 Sep 2020 16:02:09 |

US3712094

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:25:14

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-24T12:01:00', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'f838aa6c-a280-4435-9a0b-66fca853aacb' User entered 'None (0)' | System | 24 Sep 2020 16:02:09 |
| | System | 24 Sep 2020 16:02:09 |

US3712094

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:25:14

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-24T12:01:02', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'f838aa6c-a280-4435-9a0b-66fca853aacb' User entered 'None (0)' | System | 24 Sep 2020 16:02:09 |
| | System | 24 Sep 2020 16:02:09 |

US3712094

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:25:14

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-24T12:01:04', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'f838aa6c-a280-4435-9a0b-66fca853aacb' User entered 'None (0)' | System | 24 Sep 2020 16:02:09 |
| | System | 24 Sep 2020 16:02:09 |

US3712094

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:25:14

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-24T12:01:06', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'f838aa6c-a280-4435-9a0b-66fca853aacb' User entered 'None (0)' | System | 24 Sep 2020 16:02:09 |
| | System | 24 Sep 2020 16:02:09 |

US3712094

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:25:14

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) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-24T12:01:08', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'f838aa6c-a280-4435-9a0b-66fca853aacb' User entered 'No (N)' | System | 24 Sep 2020 16:02:09 |
| | System | 24 Sep 2020 16:02:09 |

US3712094

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:25:14

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-24T12:01:12', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'f838aa6c-a280-4435-9a0b-66fca853aacb' User entered '24 Sep 2020 12:01' | System | 24 Sep 2020 16:02:09 |
| | System | 24 Sep 2020 16:02:09 |

US3712094

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:25:14

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| User entered '24 Sep 2020 12:00' | System | 21 Sep 2020 16:41:47 |

US3712094

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:25:14

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| User entered '25 Sep 2020 11:59' | System | 21 Sep 2020 16:41:47 |

US3712094

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| Data entry locked. | System | 21 Sep 2020 16:41:47 |
| User entered 'Day 5' | System | 21 Sep 2020 16:41:47 |

US3712094

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:25:14

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-25T16:07:13', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'fd8f8580-4c56-44f9-a458-2f67a18a0e6d' User entered 'None (0)' | System | 25 Sep 2020 20:07:42 |
| | System | 25 Sep 2020 20:07:42 |

US3712094

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:25:14

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-25T16:07:20', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'fd8f8580-4c56-44f9-a458-2f67a18a0e6d' User entered 'None (0)' | System | 25 Sep 2020 20:07:42 |
| | System | 25 Sep 2020 20:07:42 |

US3712094

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:25:14

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-25T16:07:24', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'fd8f8580-4c56-44f9-a458-2f67a18a0e6d' User entered 'None (0)' | System | 25 Sep 2020 20:07:42 |
| | System | 25 Sep 2020 20:07:42 |

US3712094

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:25:14

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-25T16:07:26', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'fd8f8580-4c56-44f9-a458-2f67a18a0e6d' User entered 'None (0)' | System | 25 Sep 2020 20:07:42 |
| | System | 25 Sep 2020 20:07:42 |

US3712094

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:25:14

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-25T16:07:29', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'fd8f8580-4c56-44f9-a458-2f67a18a0e6d' User entered 'None (0)' | System | 25 Sep 2020 20:07:42 |
| | System | 25 Sep 2020 20:07:42 |

US3712094

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:25:14

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-25T16:07:30', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'fd8f8580-4c56-44f9-a458-2f67a18a0e6d' User entered 'None (0)' | System | 25 Sep 2020 20:07:42 |
| | System | 25 Sep 2020 20:07:42 |

US3712094

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:25:14

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) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-25T16:07:32', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'fd8f8580-4c56-44f9-a458-2f67a18a0e6d' User entered 'No (N)' | System | 25 Sep 2020 20:07:42 |
| | System | 25 Sep 2020 20:07:42 |

US3712094

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:25:14

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-25T16:07:36', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'fd8f8580-4c56-44f9-a458-2f67a18a0e6d' User entered '25 Sep 2020 16:07' | System | 25 Sep 2020 20:07:42 |
| | System | 25 Sep 2020 20:07:42 |

US3712094

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:25:14

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| User entered '25 Sep 2020 12:00' | System | 21 Sep 2020 16:41:47 |

US3712094

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:25:14

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| User entered '26 Sep 2020 11:59' | System | 21 Sep 2020 16:41:47 |

US3712094

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| Data entry locked. | System | 21 Sep 2020 16:41:47 |
| User entered 'Day 6' | System | 21 Sep 2020 16:41:47 |

US3712094

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:25:14

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-26T18:57:20', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '310540d0-ef2b-4125-b10d-fae3c7cfcc2d' User entered 'None (0)' | System | 26 Sep 2020 22:57:55 |
| | System | 26 Sep 2020 22:57:55 |

US3712094

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:25:14

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-26T18:57:34', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '310540d0-ef2b-4125-b10d-fae3c7cfcc2d' User entered 'None (0)' | System | 26 Sep 2020 22:57:55 |
| | System | 26 Sep 2020 22:57:55 |

US3712094

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:25:14

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-26T18:57:37', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '310540d0-ef2b-4125-b10d-fae3c7cfcc2d' User entered 'None (0)' | System | 26 Sep 2020 22:57:55 |
| | System | 26 Sep 2020 22:57:55 |

US3712094

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:25:14

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-26T18:57:38', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '310540d0-ef2b-4125-b10d-fae3c7cfcc2d' User entered 'None (0)' | System | 26 Sep 2020 22:57:55 |
| | System | 26 Sep 2020 22:57:55 |

US3712094

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:25:14

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-26T18:57:41', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '310540d0-ef2b-4125-b10d-fae3c7cfcc2d' User entered 'None (0)' | System | 26 Sep 2020 22:57:55 |
| | System | 26 Sep 2020 22:57:55 |

US3712094

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:25:14

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-26T18:57:44', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '310540d0-ef2b-4125-b10d-fae3c7cfcc2d' User entered 'None (0)' | System | 26 Sep 2020 22:57:55 |
| | System | 26 Sep 2020 22:57:55 |

US3712094

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:25:14

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) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-26T18:57:48', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '310540d0-ef2b-4125-b10d-fae3c7cfcc2d' User entered 'No (N)' | System | 26 Sep 2020 22:57:55 |
| | System | 26 Sep 2020 22:57:55 |

US3712094

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:25:14

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-26T18:57:52', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '310540d0-ef2b-4125-b10d-fae3c7cfcc2d' User entered '26 Sep 2020 18:57' | System | 26 Sep 2020 22:57:55 |
| | System | 26 Sep 2020 22:57:55 |

US3712094

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:25:14

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| User entered '26 Sep 2020 12:00' | System | 21 Sep 2020 16:41:47 |

US3712094

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:25:14

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| User entered '27 Sep 2020 11:59' | System | 21 Sep 2020 16:41:47 |

US3712094

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| Data entry locked. | System | 21 Sep 2020 16:41:47 |
| User entered 'Day 7' | System | 21 Sep 2020 16:41:47 |

US3712094

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:25:14

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-27T16:48:46', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '9899d3fa-0a86-4c00-80cc-c62da1c032b4' User entered 'None (0)' | System | 27 Sep 2020 20:49:10 |
| | System | 27 Sep 2020 20:49:10 |

US3712094

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:25:14

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-27T16:48:47', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '9899d3fa-0a86-4c00-80cc-c62da1c032b4' User entered 'None (0)' | System | 27 Sep 2020 20:49:10 |
| | System | 27 Sep 2020 20:49:10 |

US3712094

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:25:14

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-27T16:48:49', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '9899d3fa-0a86-4c00-80cc-c62da1c032b4' User entered 'None (0)' | System | 27 Sep 2020 20:49:10 |
| | System | 27 Sep 2020 20:49:10 |

US3712094

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:25:14

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-27T16:48:51', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '9899d3fa-0a86-4c00-80cc-c62da1c032b4' User entered 'None (0)' | System | 27 Sep 2020 20:49:10 |
| | System | 27 Sep 2020 20:49:10 |

US3712094

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:25:14

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-27T16:48:52', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '9899d3fa-0a86-4c00-80cc-c62da1c032b4' User entered 'None (0)' | System | 27 Sep 2020 20:49:10 |
| | System | 27 Sep 2020 20:49:10 |

US3712094

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:25:14

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-27T16:48:54', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '9899d3fa-0a86-4c00-80cc-c62da1c032b4' User entered 'None (0)' | System | 27 Sep 2020 20:49:10 |
| | System | 27 Sep 2020 20:49:10 |

US3712094

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:25:14

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) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-27T16:48:56', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '9899d3fa-0a86-4c00-80cc-c62da1c032b4' User entered 'No (N)' | System | 27 Sep 2020 20:49:10 |
| | System | 27 Sep 2020 20:49:10 |

US3712094

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:25:14

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-09-27T16:49:09', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '9899d3fa-0a86-4c00-80cc-c62da1c032b4' User entered '27 Sep 2020 16:49' | System | 27 Sep 2020 20:49:10 |
| | System | 27 Sep 2020 20:49:10 |

US3712094

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:25:14

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| User entered '27 Sep 2020 12:00' | System | 21 Sep 2020 16:41:47 |

US3712094

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:25:14

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| User entered '28 Sep 2020 11:59' | System | 21 Sep 2020 16:41:47 |

US3712094

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:25:14

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:39:11 |
| Data hard unlocked. | (b) (4), (b) (6) | 08 Apr 2021 22:42:27 |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:27:43 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:20:50 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:17:57 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 06 Oct 2020 19:30:57 |

US3712094

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:25:14

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:39:11 |
| Data hard unlocked. | (b) (4), (b) (6) | 08 Apr 2021 22:42:27 |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:27:43 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:20:50 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:17:57 |
| User entered '28 Sep 2020' | (b) (4), (b) (6) | 06 Oct 2020 19:30:57 |

US3712094

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:25:14

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:39:11 |
| Data hard unlocked. | (b) (4), (b) (6) | 08 Apr 2021 22:42:27 |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:27:43 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:20:50 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:17:57 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4), (b) (6) | 06 Oct 2020 19:30:57 |

US3712094

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:25:14

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:39:11 |
| Data hard unlocked. | (b) (4), (b) (6) | 08 Apr 2021 22:42:27 |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:27:43 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:20:50 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:17:57 |
| User entered empty. | (b) (4), (b) (6) | 06 Oct 2020 19:30:57 |

US3712094

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:25:14

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:39:11 |
| Data hard unlocked. | (b) (4), (b) (6) | 08 Apr 2021 22:42:21 |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:27:43 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:20:50 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:18:02 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 06 Oct 2020 19:31:11 |

US3712094

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:25:14

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:39:11 |
| Data hard unlocked. | (b) (4), (b) (6) | 08 Apr 2021 22:42:21 |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:27:43 |
| User entered 'l' | System | 06 Oct 2020 19:31:11 |

US3712094

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:25:14

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:39:11 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:34:46 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:20:50 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 06 Oct 2020 19:34:06 |

US3712094

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:25:14

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:39:11 |
| User signature succeeded. | William Smith (b) (4) | 18 Apr 2021 23:29:00 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 14 Apr 2021 19:23:14 |
| User closed query 'Please confirm, as subject did not answer on 05Oct2020, but answered on 06Oct2020. if confirmed, please update.' (Site from CRA). | (b) (4), (b) (6) | 14 Apr 2021 19:22:46 |
| Query 'Please confirm, as subject did not answer on 05Oct2020, but answered on 06Oct2020. if confirmed, please update.' answered with 'updated' (Site from CRA). | (b) (4), (b) (6) | 19 Mar 2021 13:23:23 |
| Signature has been broken. | (b) (4), (b) (6) | 19 Mar 2021 13:23:19 |
| User entered '06 Oct 2020' reason for change: Data Entry Error | (b) (4), (b) (6) | 19 Mar 2021 13:23:19 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 25 Feb 2021 15:38:24 |
| User opened query 'Please confirm, as subject did not answer on 05Oct2020, but answered on 06Oct2020. if confirmed, please update.' (Site from CRA). | (b) (4), (b) (6) | 25 Feb 2021 15:35:19 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:34:46 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:20:50 |
| User entered '05 Oct 2020' | (b) (4) (b) (4), (b) (6) | 06 Oct 2020 19:34:06 |

US3712094

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:25:14

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:39:11 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:34:46 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:20:50 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) (b) (4), (b) (6) | 06 Oct 2020 19:34:06 |

US3712094

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:25:14

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:39:11 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:34:46 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:20:50 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 06 Oct 2020 19:34:06 |

US3712094

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:25:14

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:39:11 |
| Data hard unlocked. | (b) (4), (b) (6) | 08 Apr 2021 22:40:06 |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:27:43 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:38:20 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:20:50 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 06 Oct 2020 19:34:09 |

US3712094

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:25:14

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:39:11 |
| Data hard unlocked. | (b) (4), (b) (6) | 08 Apr 2021 22:40:06 |
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 07:27:43 |
| User entered 'l' | System | 06 Oct 2020 19:34:09 |

US3712094

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:25:14

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:04:12 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:39:03 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:20:50 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 09 Nov 2020 14:20:50 |

US3712094

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:25:14

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:04:12 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:39:03 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:20:50 |
| User entered '12 Oct 2020' | (b) (4) (b) (4), (b) (6) | 09 Nov 2020 14:20:50 |

US3712094

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:25:14

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:04:12 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:39:03 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:20:50 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) (b) (4), (b) (6) | 09 Nov 2020 14:20:50 |

US3712094

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:25:14

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:04:12 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:39:03 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:20:50 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 09 Nov 2020 14:20:50 |

US3712094

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:25:14

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:04:12 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:39:19 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:20:50 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 19 Oct 2020 15:20:54 |

US3712094

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:25:14

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:04:12 |
| User entered 'I' | System | 19 Oct 2020 15:20:54 |

US3712094

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:25:14

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:40:48 |
| | | |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| | (b) (4) | |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 19 Oct 2020 15:21:02 |
| | | |

US3712094

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:40:48 |
| | | |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| | (b) (4) | |
| User entered '19 Oct 2020' | (b) (4), (b) (6) | 19 Oct 2020 15:21:02 |
| | | |

US3712094

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:40:48 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| User entered 'Clinic (Clinic)' | (b) (4), (b) (6) | 19 Oct 2020 15:21:02 |

US3712094

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:25:14

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| User entered 'VISIT2' | System | 19 Oct 2020 15:21:02 |

US3712094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:14

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| User accepted default value 'Pre-Dose (PREDOSE)' | (b) (4), (b) (6) | 20 Oct 2020 12:32:46 |
| | | |

US3712094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:14

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:42:16 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 20 Oct 2020 12:32:46 |

US3712094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:14

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:42:16 |
| | | |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| | (b) (4) | |
| User entered '19 Oct 2020' | (b) (4), (b) (6) | 20 Oct 2020 12:32:46 |
| | | |

US3712094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:14

[Time of assessment \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:42:16 |
| | | |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| | (b) (4) | |
| User entered '10:22' | (b) (4), (b) (6) | 20 Oct 2020 12:32:46 |
| | | |

US3712094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| User entered '19 Oct 2020 10:22' | System | 20 Oct 2020 12:32:46 |

US3712094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:14

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:42:16 |
| | | |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| | (b) (4) | |
| User entered '37.2' C | (b) (4), (b) (6) | 20 Oct 2020 12:32:46 |
| | | |

US3712094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:14

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:42:16 |
| | | |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| | (b) (4) | |
| User entered 'Oral (Oral)' | (b) (4), (b) (6) | 20 Oct 2020 12:32:46 |
| | | |

US3712094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:14

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:42:16 |
| | | |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| | (b) (4) | |
| User entered empty. | (b) (4), (b) (6) | 20 Oct 2020 12:32:46 |
| | | |

US3712094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:14

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:42:16 |
| | | |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| | (b) (4) | |
| User entered '71' | (b) (4), (b) (6) | 20 Oct 2020 12:32:46 |
| | | |

US3712094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:14

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| User entered 'bpm' | System | 20 Oct 2020 12:32:46 |

US3712094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:42:16 |
| | | |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| | (b) (4) | |
| User entered '16' | (b) (4), (b) (6) | 20 Oct 2020 12:32:46 |
| | | |

US3712094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:14

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| User entered 'breaths/min' | System | 20 Oct 2020 12:32:46 |

US3712094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:42:16 |
| | | |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| | (b) (4) | |
| User entered '116' | (b) (4), (b) (6) | 20 Oct 2020 12:32:46 |
| | | |

US3712094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:14

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| User entered 'mmHg' | System | 20 Oct 2020 12:32:46 |

US3712094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:14

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:42:16 |
| | | |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| | (b) (4) | |
| User entered '68' | (b) (4), (b) (6) | 20 Oct 2020 12:32:46 |
| | | |

US3712094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:14

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| User entered 'mmHg' | System | 20 Oct 2020 12:32:46 |

US3712094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:14

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| User accepted default value 'Post-Dose (POSTDOSE)' | (b) (4), (b) (6) | 20 Oct 2020 12:32:46 |
| | | |

US3712094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:14

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:42:16 |
| | | |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| | (b) (4) | |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 20 Oct 2020 12:32:46 |
| | | |

US3712094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:14

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:42:16 |
| | | |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| | (b) (4) | |
| User entered '19 Oct 2020' | (b) (4), (b) (6) | 20 Oct 2020 12:32:46 |
| | | |

US3712094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:14

[Time of assessment \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:42:16 |
| | | |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| | (b) (4) | |
| User entered '11:51' | (b) (4), (b) (6) | 20 Oct 2020 12:32:46 |
| | | |

US3712094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| User entered '19 Oct 2020 11:51' | System | 20 Oct 2020 12:32:46 |

US3712094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:14

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:42:16 |
| | | |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| | (b) (4) | |
| User entered '37.0' C | (b) (4), (b) (6) | 20 Oct 2020 12:32:46 |
| | | |

US3712094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:14

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:42:16 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| User entered 'Oral (Oral)' | (b) (4), (b) (6) | 20 Oct 2020 12:32:46 |

US3712094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:14

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:42:16 |
| | | |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| | (b) (4) | |
| User entered empty. | (b) (4), (b) (6) | 20 Oct 2020 12:32:46 |
| | | |

US3712094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:14

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:42:16 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| User entered '83' | (b) (4), (b) (6) | 20 Oct 2020 12:32:46 |

US3712094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:14

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| User entered 'bpm' | System | 20 Oct 2020 12:32:46 |

US3712094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:42:16 |
| | | |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| | (b) (4) | |
| User entered '16' | (b) (4), (b) (6) | 20 Oct 2020 12:32:46 |
| | | |

US3712094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:14

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| User entered 'breaths/min' | System | 20 Oct 2020 12:32:46 |

US3712094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:42:16 |
| | | |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| | (b) (4) | |
| User entered '105' | (b) (4), (b) (6) | 20 Oct 2020 12:32:46 |
| | | |

US3712094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:14

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| User entered 'mmHg' | System | 20 Oct 2020 12:32:46 |

US3712094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:14

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:42:16 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| User entered '72' | (b) (4), (b) (6) | 20 Oct 2020 12:32:46 |

US3712094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:14

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| User entered 'mmHg' | System | 20 Oct 2020 12:32:46 |

US3712094

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:25:14

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:42:22 |
| | | |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| | (b) (4) | |
| User entered 'No (N)' | (b) (4), (b) (6) | 19 Oct 2020 15:21:29 |
| | | |

US3712094

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:25:14

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:42:22 |
| | | |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| | (b) (4) | |
| User entered empty. | (b) (4), (b) (6) | 19 Oct 2020 15:21:29 |
| | | |

US3712094

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:25:14

[Was the pregnancy test performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:42:28 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 19 Oct 2020 15:21:15 |

US3712094

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:25:14

Date of test (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:42:28 |
| | | |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| | (b) (4) | |
| User entered '19 Oct 2020' | (b) (4), (b) (6) | 19 Oct 2020 15:21:15 |
| | | |

US3712094

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:25:14

[Test performed](#)

| Audit | User | Time (GMT) |
|------------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:42:28 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| User entered 'Urine (URINE)' | (b) (4), (b) (6) | 19 Oct 2020 15:21:15 |

US3712094

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:25:14

[Result](#)

| Audit | User | Time (GMT) |
|------------------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:42:28 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| User entered 'Negative (NEGATIVE)' | (b) (4), (b) (6) | 19 Oct 2020 15:21:15 |

US3712094

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:25:14

[Was FSH sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:42:28 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| User entered 'No (N)' | (b) (4), (b) (6) | 19 Oct 2020 15:21:15 |

US3712094

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:25:14

[Collection date](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:42:28 |
| | | |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| | (b) (4) | |
| User entered empty. | (b) (4), (b) (6) | 19 Oct 2020 15:21:15 |
| | | |

US3712094

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:25:14

[Collection time](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:42:28 |
| | | |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| | (b) (4) | |
| User entered empty. | (b) (4), (b) (6) | 19 Oct 2020 15:21:15 |
| | | |

US3712094

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| User entered empty. | System | 19 Oct 2020 15:21:15 |

US3712094

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:25:14

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:43:04 |
| | | |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| | (b) (4) | |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 19 Oct 2020 15:22:10 |
| | | |

US3712094

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:25:14

[If No, reason not given](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:43:04 |
| | | |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| | (b) (4) | |
| User entered empty. | (b) (4), (b) (6) | 19 Oct 2020 15:22:10 |
| | | |

US3712094

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:25:14

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) | 30 Apr 2021 01:58:00 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:43:04 |
| | | |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| | (b) (4) | |
| User entered empty. | (b) (4), (b) (6) | 19 Oct 2020 15:22:10 |
| | | |

US3712094

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:25:14

[What was the study treatment?](#)

| Audit | User | Time (GMT) |
|-------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| User entered 'MRNA-1273 OR PLACEBO' | System | 19 Oct 2020 15:22:10 |

US3712094

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:25:14

What was the treatment date? (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:43:04 |
| | | |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| | (b) (4) | |
| User entered '19 Oct 2020' | (b) (4), (b) (6) | 19 Oct 2020 15:22:10 |
| | | |

US3712094

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:43:04 |
| | | |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| | (b) (4) | |
| User entered '11:16' | (b) (4), (b) (6) | 19 Oct 2020 15:22:10 |
| | | |

US3712094

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| User entered '19 Oct 2020 11:16' | System | 19 Oct 2020 15:22:10 |

US3712094

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|------------------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:43:04 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| User entered 'Left Arm (LEFT ARM)' | (b) (4), (b) (6) | 19 Oct 2020 15:22:10 |

US3712094

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:43:04 |
| | | |
| User entered 'ONCE' | System | 19 Oct 2020 15:22:10 |

US3712094

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:25:14

[What was the route of administration for the study treatment?](#)

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| User entered 'INTRAMUSCULAR' | System | 19 Oct 2020 15:22:10 |

US3712094

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:25:14

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:43:15 |
| | | |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| | (b) (4) | |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 19 Oct 2020 15:21:42 |
| | | |

US3712094

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:25:14

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:43:15 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| User entered '19 Oct 2020' | (b) (4), (b) (6) | 19 Oct 2020 15:21:42 |

US3712094

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:25:14

[Collection time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:43:15 |
| | | |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| | (b) (4) | |
| User entered '10:46' | (b) (4), (b) (6) | 19 Oct 2020 15:21:42 |
| | | |

US3712094

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| User entered '19 Oct 2020 10:46' | System | 19 Oct 2020 15:21:42 |

US3712094

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:43:24 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| User entered '19 Oct 2020' | (b) (4), (b) (6) | 19 Oct 2020 15:21:54 |

US3712094

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:25:14

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | (b) (4), (b) (6) | 19 Oct 2020 15:21:54 |
| | | |

US3712094

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:25:14

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:43:24 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 19 Oct 2020 15:21:54 |

US3712094

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:25:14

[Collection time \(00:00 - 23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:43:24 |
| | | |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| | (b) (4) | |
| User entered '10:49' | (b) (4), (b) (6) | 19 Oct 2020 15:21:54 |
| | | |

US3712094

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| User entered '19 Oct 2020 10:49' | System | 19 Oct 2020 15:21:54 |

US3712094

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:25:14

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | (b) (4), (b) (6) | 19 Oct 2020 15:21:54 |
| | | |

US3712094

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:25:14

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:43:24 |
| | | |
| User signature succeeded. | William Smith (b) (4) | 20 Feb 2021 17:12:15 |
| | (b) (4) | |
| Signature has been broken. | (b) (4), (b) (6) | 15 Feb 2021 21:00:38 |
| | | |
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4), (b) (6) | 15 Feb 2021 21:00:38 |
| | | |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| | (b) (4) | |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 19 Oct 2020 15:21:54 |
| | | |

US3712094

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:25:14

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:43:24 |
| | | |
| User signature succeeded. | William Smith (b) (4) | 20 Feb 2021 17:12:15 |
| | (b) (4) | |
| Signature has been broken. | (b) (4), (b) (6) | 15 Feb 2021 21:00:38 |
| | | |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6) | 15 Feb 2021 21:00:38 |
| | | |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| | (b) (4) | |
| User entered '10:49' | (b) (4), (b) (6) | 19 Oct 2020 15:21:54 |
| | | |

US3712094

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| User entered empty. | System | 15 Feb 2021 21:00:38 |
| User entered '19 Oct 2020 10:49' | System | 19 Oct 2020 15:21:54 |

US3712094

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:25:14

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:43:29 |
| | | |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| | (b) (4) | |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 19 Oct 2020 15:21:56 |
| | | |

US3712094

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:25:14

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 01:58:00 |
| | | |
| User entered '1' | System | 19 Oct 2020 15:21:56 |

US3712094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| Data entry locked. | System | 19 Oct 2020 15:22:10 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 19 Oct 2020 15:22:10 |

US3712094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:25:14

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-19T11:50:41', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '6ab0ec67-b458-47e4-8375-630074063897' User entered 'Yes (Y)' | System | 19 Oct 2020 15:50:54 |
| | System | 19 Oct 2020 15:50:54 |

US3712094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:25:14

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-19T11:50:44', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '6ab0ec67-b458-47e4-8375-630074063897' User entered '98.6' | System | 19 Oct 2020 15:50:54 |
| | System | 19 Oct 2020 15:50:54 |

US3712094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-19T11:50:47', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '6ab0ec67-b458-47e4-8375-630074063897' | System | 19 Oct 2020 15:50:54 |
| User entered 'No (N)' | System | 19 Oct 2020 15:50:54 |

US3712094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:25:14

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-19T11:50:50', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '6ab0ec67-b458-47e4-8375-630074063897' User entered '19 Oct 2020 11:50' | System | 19 Oct 2020 15:50:54 |
| | System | 19 Oct 2020 15:50:54 |

US3712094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:25:14

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| User entered '19 Oct 2020 11:36' | System | 19 Oct 2020 15:22:10 |

US3712094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:25:14

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| User entered '19 Oct 2020 14:06' | System | 19 Oct 2020 15:22:10 |

US3712094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| Data entry locked. | System | 19 Oct 2020 15:22:10 |
| User entered 'Day 1, after vaccination (at home)' | System | 19 Oct 2020 15:22:10 |

US3712094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:25:14

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-19T22:17:34', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '536ff00e-4cb3-4842-88b4-6d6c7c6951ae' User entered 'Yes (Y)' | System | 20 Oct 2020 02:17:48 |
| | System | 20 Oct 2020 02:17:48 |

US3712094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:25:14

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-19T22:17:38', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '536ff00e-4cb3-4842-88b4-6d6c7c6951ae' User entered '98.6' | System | 20 Oct 2020 02:17:48 |
| | System | 20 Oct 2020 02:17:48 |

US3712094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-19T22:17:41', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '536ff00e-4cb3-4842-88b4-6d6c7c6951ae' User entered 'No (N)' | System | 20 Oct 2020 02:17:48 |
| | System | 20 Oct 2020 02:17:48 |

US3712094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:25:14

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-19T22:17:45', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '536ff00e-4cb3-4842-88b4-6d6c7c6951ae' User entered '19 Oct 2020 22:17' | System | 20 Oct 2020 02:17:48 |
| | System | 20 Oct 2020 02:17:48 |

US3712094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:25:14

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| User entered '19 Oct 2020 15:01' | System | 19 Oct 2020 15:22:10 |

US3712094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:25:14

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| User entered '20 Oct 2020 11:59' | System | 19 Oct 2020 15:22:10 |

US3712094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| Data entry locked. | System | 19 Oct 2020 15:22:10 |
| User entered 'Day 2' | System | 19 Oct 2020 15:22:10 |

US3712094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:25:14

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-20T21:11:09', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '07bddbfc-31d8-4307-9619-fd652b3e9f41' User entered 'Yes (Y)' | System | 21 Oct 2020 01:11:23 |
| | System | 21 Oct 2020 01:11:23 |

US3712094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:25:14

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-20T21:11:13', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '07bddbfc-31d8-4307-9619-fd652b3e9f41' User entered '98.4' | System | 21 Oct 2020 01:11:23 |
| | System | 21 Oct 2020 01:11:23 |

US3712094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-20T21:11:16', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '07bddbfc-31d8-4307-9619-fd652b3e9f41' User entered 'No (N)' | System | 21 Oct 2020 01:11:23 |
| | System | 21 Oct 2020 01:11:23 |

US3712094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:25:14

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-20T21:11:22', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '07bddbfc-31d8-4307-9619-fd652b3e9f41' User entered '20 Oct 2020 21:11' | System | 21 Oct 2020 01:11:23 |
| | System | 21 Oct 2020 01:11:23 |

US3712094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:25:14

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| User entered '20 Oct 2020 12:00' | System | 19 Oct 2020 15:22:10 |

US3712094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:25:14

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| User entered '21 Oct 2020 11:59' | System | 19 Oct 2020 15:22:10 |

US3712094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| Data entry locked. | System | 19 Oct 2020 15:22:10 |
| User entered 'Day 3' | System | 19 Oct 2020 15:22:10 |

US3712094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:25:14

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-21T17:28:14', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'cfc085c7-7c82-4fa3-8aa2-bb81890c7247' | System | 21 Oct 2020 21:28:26 |
| User entered 'Yes (Y)' | System | 21 Oct 2020 21:28:26 |

US3712094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:25:14

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-21T17:28:18', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'cfc085c7-7c82-4fa3-8aa2-bb81890c7247' User entered '98.1' | System | 21 Oct 2020 21:28:26 |
| | System | 21 Oct 2020 21:28:26 |

US3712094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-21T17:28:20', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'cfc085c7-7c82-4fa3-8aa2-bb81890c7247' | System | 21 Oct 2020 21:28:26 |
| User entered 'No (N)' | System | 21 Oct 2020 21:28:26 |

US3712094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:25:14

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-21T17:28:25', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'cfc085c7-7c82-4fa3-8aa2-bb81890c7247' User entered '21 Oct 2020 17:28' | System | 21 Oct 2020 21:28:26 |
| | System | 21 Oct 2020 21:28:26 |

US3712094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:25:14

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| User entered '21 Oct 2020 12:00' | System | 19 Oct 2020 15:22:10 |

US3712094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:25:14

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| User entered '22 Oct 2020 11:59' | System | 19 Oct 2020 15:22:10 |

US3712094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| Data entry locked. | System | 19 Oct 2020 15:22:10 |
| User entered 'Day 4' | System | 19 Oct 2020 15:22:10 |

US3712094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:25:14

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-22T20:28:49', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '2fdeedc5-b47c-42c3-b0a7-70922f6fe05f' User entered 'Yes (Y)' | System | 23 Oct 2020 00:29:02 |
| | System | 23 Oct 2020 00:29:02 |

US3712094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:25:14

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-22T20:28:52', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '2fdeedc5-b47c-42c3-b0a7-70922f6fe05f' User entered '98.1' | System | 23 Oct 2020 00:29:02 |
| | System | 23 Oct 2020 00:29:02 |

US3712094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-22T20:28:54', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '2fdeedc5-b47c-42c3-b0a7-70922f6fe05f' User entered 'No (N)' | System | 23 Oct 2020 00:29:02 |
| | System | 23 Oct 2020 00:29:02 |

US3712094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:25:14

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-22T20:28:59', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '2fdeedc5-b47c-42c3-b0a7-70922f6fe05f' User entered '22 Oct 2020 20:28' | System | 23 Oct 2020 00:29:02 |
| | System | 23 Oct 2020 00:29:02 |

US3712094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:25:14

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| User entered '22 Oct 2020 12:00' | System | 19 Oct 2020 15:22:10 |

US3712094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:25:14

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| User entered '23 Oct 2020 11:59' | System | 19 Oct 2020 15:22:10 |

US3712094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| Data entry locked. | System | 19 Oct 2020 15:22:10 |
| User entered 'Day 5' | System | 19 Oct 2020 15:22:10 |

US3712094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:25:14

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-23T18:19:43', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '4acf31d8-b8d5-4b82-a591-583178398e8f' User entered 'Yes (Y)' | System | 23 Oct 2020 22:19:59 |
| | System | 23 Oct 2020 22:19:59 |

US3712094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:25:14

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-23T18:19:46', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '4acf31d8-b8d5-4b82-a591-583178398e8f' User entered '98.1' | System | 23 Oct 2020 22:19:59 |
| | System | 23 Oct 2020 22:19:59 |

US3712094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-23T18:19:48', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '4acf31d8-b8d5-4b82-a591-583178398e8f' User entered 'No (N)' | System | 23 Oct 2020 22:19:59 |
| | System | 23 Oct 2020 22:19:59 |

US3712094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:25:14

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-23T18:19:54', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '4acf31d8-b8d5-4b82-a591-583178398e8f' User entered '23 Oct 2020 18:19' | System | 23 Oct 2020 22:19:59 |
| | System | 23 Oct 2020 22:19:59 |

US3712094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:25:14

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| User entered '23 Oct 2020 12:00' | System | 19 Oct 2020 15:22:10 |

US3712094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:25:14

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| User entered '24 Oct 2020 11:59' | System | 19 Oct 2020 15:22:10 |

US3712094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| Data entry locked. | System | 19 Oct 2020 15:22:10 |
| User entered 'Day 6' | System | 19 Oct 2020 15:22:10 |

US3712094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:25:14

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-24T19:38:32', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '038ee080-7e8f-4bd4-b124-2891131c0e36' User entered 'Yes (Y)' | System | 24 Oct 2020 23:38:42 |
| | System | 24 Oct 2020 23:38:42 |

US3712094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:25:14

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-24T19:38:35', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '038ee080-7e8f-4bd4-b124-2891131c0e36' User entered '98.2' | System | 24 Oct 2020 23:38:42 |
| | System | 24 Oct 2020 23:38:42 |

US3712094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-24T19:38:36', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '038ee080-7e8f-4bd4-b124-2891131c0e36' User entered 'No (N)' | System | 24 Oct 2020 23:38:42 |
| | System | 24 Oct 2020 23:38:42 |

US3712094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:25:14

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-24T19:38:39', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '038ee080-7e8f-4bd4-b124-2891131c0e36' User entered '24 Oct 2020 19:38' | System | 24 Oct 2020 23:38:42 |
| | System | 24 Oct 2020 23:38:42 |

US3712094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:25:14

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| User entered '24 Oct 2020 12:00' | System | 19 Oct 2020 15:22:10 |

US3712094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:25:14

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| User entered '25 Oct 2020 11:59' | System | 19 Oct 2020 15:22:10 |

US3712094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| Data entry locked. | System | 19 Oct 2020 15:22:10 |
| User entered 'Day 7' | System | 19 Oct 2020 15:22:10 |

US3712094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:25:14

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-25T22:06:48', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'e7b9f29f-e6e2-405f-b67d-54359b47e9c6' User entered 'Yes (Y)' | System | 26 Oct 2020 02:07:09 |
| | System | 26 Oct 2020 02:07:09 |

US3712094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:25:14

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-25T22:06:55', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'e7b9f29f-e6e2-405f-b67d-54359b47e9c6' User entered '98.1' | System | 26 Oct 2020 02:07:09 |
| | System | 26 Oct 2020 02:07:09 |

US3712094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-25T22:07:00', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'e7b9f29f-e6e2-405f-b67d-54359b47e9c6' | System | 26 Oct 2020 02:07:09 |
| User entered 'No (N)' | System | 26 Oct 2020 02:07:09 |

US3712094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:25:14

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-25T22:07:04', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'e7b9f29f-e6e2-405f-b67d-54359b47e9c6' User entered '25 Oct 2020 22:07' | System | 26 Oct 2020 02:07:09 |
| | System | 26 Oct 2020 02:07:09 |

US3712094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:25:14

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| User entered '25 Oct 2020 12:00' | System | 19 Oct 2020 15:22:10 |

US3712094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:25:14

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| User entered '26 Oct 2020 11:59' | System | 19 Oct 2020 15:22:10 |

US3712094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| Data entry locked. | System | 19 Oct 2020 15:22:10 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 19 Oct 2020 15:22:10 |

US3712094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:25:14

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-19T11:47:02', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'ad8fbc2a-0c20-4bf2-aefe-9f948191c58e' User entered 'None (1)' | System | 19 Oct 2020 15:47:17 |
| | System | 19 Oct 2020 15:47:17 |

US3712094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:25:14

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-19T11:47:04', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'ad8fbc2a-0c20-4bf2-aefe-9f948191c58e' User entered 'No (N)' | System | 19 Oct 2020 15:47:17 |
| | System | 19 Oct 2020 15:47:17 |

US3712094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-19T11:47:07', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'ad8fbc2a-0c20-4bf2-aefe-9f948191c58e' User entered 'No (N)' | System | 19 Oct 2020 15:47:17 |
| | System | 19 Oct 2020 15:47:17 |

US3712094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:25:14

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-19T11:47:09', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'ad8fbc2a-0c20-4bf2-ae9f-9f948191c58e' | System | 19 Oct 2020 15:47:17 |
| User entered 'None (1)' | System | 19 Oct 2020 15:47:17 |

US3712094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:25:14

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-19T11:47:14', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'ad8fbc2a-0c20-4bf2-aefe-9f948191c58e' User entered '19 Oct 2020 11:47' | System | 19 Oct 2020 15:47:17 |
| | System | 19 Oct 2020 15:47:17 |

US3712094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:25:14

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| User entered '19 Oct 2020 11:36' | System | 19 Oct 2020 15:22:10 |

US3712094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:25:14

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| User entered '19 Oct 2020 14:06' | System | 19 Oct 2020 15:22:10 |

US3712094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| Data entry locked. | System | 19 Oct 2020 15:22:10 |
| User entered 'Day 1, after vaccination (at home)' | System | 19 Oct 2020 15:22:10 |

US3712094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:25:14

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-19T22:17:49', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'e2682222-3fcf-4835-b57c-8cad72f57874' User entered 'None (1)' | System | 20 Oct 2020 02:18:02 |
| | System | 20 Oct 2020 02:18:02 |

US3712094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:25:14

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-19T22:17:51', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'e2682222-3fcf-4835-b57c-8cad72f57874' | System | 20 Oct 2020 02:18:02 |
| User entered 'No (N)' | System | 20 Oct 2020 02:18:02 |

US3712094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-19T22:17:53', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'e2682222-3fcf-4835-b57c-8cad72f57874' | System | 20 Oct 2020 02:18:02 |
| User entered 'No (N)' | System | 20 Oct 2020 02:18:02 |

US3712094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:25:14

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-19T22:17:55', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'e2682222-3fcf-4835-b57c-8cad72f57874' | System | 20 Oct 2020 02:18:02 |
| User entered 'None (1)' | System | 20 Oct 2020 02:18:02 |

US3712094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:25:14

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-19T22:17:58', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'e2682222-3fcf-4835-b57c-8cad72f57874' User entered '19 Oct 2020 22:17' | System | 20 Oct 2020 02:18:02 |
| | System | 20 Oct 2020 02:18:02 |

US3712094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:25:14

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| User entered '19 Oct 2020 15:01' | System | 19 Oct 2020 15:22:10 |

US3712094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:25:14

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| User entered '20 Oct 2020 11:59' | System | 19 Oct 2020 15:22:10 |

US3712094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| Data entry locked. | System | 19 Oct 2020 15:22:10 |
| User entered 'Day 2' | System | 19 Oct 2020 15:22:10 |

US3712094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:25:14

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-20T21:11:26', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'dffe3791-65e5-4fc7-be49-9c44b6232321' | System | 21 Oct 2020 01:11:36 |
| User entered 'None (1)' | System | 21 Oct 2020 01:11:36 |

US3712094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:25:14

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-20T21:11:28', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'dffe3791-65e5-4fc7-be49-9c44b6232321' User entered 'No (N)' | System | 21 Oct 2020 01:11:36 |
| | System | 21 Oct 2020 01:11:36 |

US3712094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-20T21:11:30', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'dffe3791-65e5-4fc7-be49-9c44b6232321' User entered 'No (N)' | System | 21 Oct 2020 01:11:36 |
| | System | 21 Oct 2020 01:11:36 |

US3712094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:25:14

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-20T21:11:32', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'dffe3791-65e5-4fc7-be49-9c44b6232321' | System | 21 Oct 2020 01:11:36 |
| User entered 'None (1)' | System | 21 Oct 2020 01:11:36 |

US3712094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:25:14

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-20T21:11:35', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'dffe3791-65e5-4fc7-be49-9c44b6232321' User entered '20 Oct 2020 21:11' | System | 21 Oct 2020 01:11:36 |
| | System | 21 Oct 2020 01:11:36 |

US3712094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:25:14

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| User entered '20 Oct 2020 12:00' | System | 19 Oct 2020 15:22:10 |

US3712094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:25:14

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| User entered '21 Oct 2020 11:59' | System | 19 Oct 2020 15:22:10 |

US3712094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| Data entry locked. | System | 19 Oct 2020 15:22:10 |
| User entered 'Day 3' | System | 19 Oct 2020 15:22:10 |

US3712094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:25:14

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-21T17:28:29', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'f7503fc8-36ed-41f9-93f2-00dd9adfc0e0' User entered 'None (1)' | System | 21 Oct 2020 21:28:42 |
| | System | 21 Oct 2020 21:28:42 |

US3712094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:25:14

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-21T17:28:32', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'f7503fc8-36ed-41f9-93f2-00dd9adfc0e0' | System | 21 Oct 2020 21:28:42 |
| User entered 'No (N)' | System | 21 Oct 2020 21:28:42 |

US3712094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-21T17:28:34', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'f7503fc8-36ed-41f9-93f2-00dd9adfc0e0' User entered 'No (N)' | System | 21 Oct 2020 21:28:42 |
| | System | 21 Oct 2020 21:28:42 |

US3712094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:25:14

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-21T17:28:36', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'f7503fc8-36ed-41f9-93f2-00dd9adfc0e0' | System | 21 Oct 2020 21:28:42 |
| User entered 'None (1)' | System | 21 Oct 2020 21:28:42 |

US3712094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:25:14

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-21T17:28:41', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'f7503fc8-36ed-41f9-93f2-00dd9adfc0e0' User entered '21 Oct 2020 17:28' | System | 21 Oct 2020 21:28:42 |
| | System | 21 Oct 2020 21:28:42 |

US3712094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:25:14

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| User entered '21 Oct 2020 12:00' | System | 19 Oct 2020 15:22:10 |

US3712094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:25:14

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| User entered '22 Oct 2020 11:59' | System | 19 Oct 2020 15:22:10 |

US3712094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| Data entry locked. | System | 19 Oct 2020 15:22:10 |
| User entered 'Day 4' | System | 19 Oct 2020 15:22:10 |

US3712094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:25:14

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-22T20:29:03', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '1b6d354a-f355-46b9-ab05-f318e26b0a8d' User entered 'None (1)' | System | 23 Oct 2020 00:29:18 |
| | System | 23 Oct 2020 00:29:18 |

US3712094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:25:14

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-22T20:29:05', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '1b6d354a-f355-46b9-ab05-f318e26b0a8d' User entered 'No (N)' | System | 23 Oct 2020 00:29:18 |
| | System | 23 Oct 2020 00:29:18 |

US3712094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-22T20:29:07', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '1b6d354a-f355-46b9-ab05-f318e26b0a8d' User entered 'No (N)' | System | 23 Oct 2020 00:29:18 |
| | System | 23 Oct 2020 00:29:18 |

US3712094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:25:14

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-22T20:29:12', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '1b6d354a-f355-46b9-ab05-f318e26b0a8d' User entered 'None (1)' | System | 23 Oct 2020 00:29:18 |
| | System | 23 Oct 2020 00:29:18 |

US3712094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:25:14

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-22T20:29:15', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '1b6d354a-f355-46b9-ab05-f318e26b0a8d' User entered '22 Oct 2020 20:29' | System | 23 Oct 2020 00:29:18 |
| | System | 23 Oct 2020 00:29:18 |

US3712094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:25:14

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| User entered '22 Oct 2020 12:00' | System | 19 Oct 2020 15:22:10 |

US3712094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:25:14

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| User entered '23 Oct 2020 11:59' | System | 19 Oct 2020 15:22:10 |

US3712094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| Data entry locked. | System | 19 Oct 2020 15:22:10 |
| User entered 'Day 5' | System | 19 Oct 2020 15:22:10 |

US3712094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:25:14

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-23T18:19:27', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '745e0423-f186-4864-8bf3-ca536f06e1ea' User entered 'None (1)' | System | 23 Oct 2020 22:19:38 |
| | System | 23 Oct 2020 22:19:38 |

US3712094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:25:14

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-23T18:19:29', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '745e0423-f186-4864-8bf3-ca536f06e1ea' User entered 'No (N)' | System | 23 Oct 2020 22:19:38 |
| | System | 23 Oct 2020 22:19:38 |

US3712094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-23T18:19:31', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '745e0423-f186-4864-8bf3-ca536f06e1ea' User entered 'No (N)' | System | 23 Oct 2020 22:19:38 |
| | System | 23 Oct 2020 22:19:38 |

US3712094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:25:14

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-23T18:19:33', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '745e0423-f186-4864-8bf3-ca536f06e1ea' User entered 'None (1)' | System | 23 Oct 2020 22:19:38 |
| | System | 23 Oct 2020 22:19:38 |

US3712094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:25:14

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-23T18:19:37', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '745e0423-f186-4864-8bf3-ca536f06e1ea' User entered '23 Oct 2020 18:19' | System | 23 Oct 2020 22:19:38 |
| | System | 23 Oct 2020 22:19:38 |

US3712094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:25:14

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| User entered '23 Oct 2020 12:00' | System | 19 Oct 2020 15:22:10 |

US3712094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:25:14

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| User entered '24 Oct 2020 11:59' | System | 19 Oct 2020 15:22:10 |

US3712094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| Data entry locked. | System | 19 Oct 2020 15:22:10 |
| User entered 'Day 6' | System | 19 Oct 2020 15:22:10 |

US3712094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:25:14

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-24T19:38:42', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'dd148bd6-d5bf-4e2c-b2dd-8e025c87b1e3' | System | 24 Oct 2020 23:38:53 |
| User entered 'None (1)' | System | 24 Oct 2020 23:38:53 |

US3712094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-24T19:38:44', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'dd148bd6-d5bf-4e2c-b2dd-8e025c87b1e3' User entered 'No (N)' | System | 24 Oct 2020 23:38:53 |
| | System | 24 Oct 2020 23:38:53 |

US3712094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-24T19:38:46', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'dd148bd6-d5bf-4e2c-b2dd-8e025c87b1e3' User entered 'No (N)' | System | 24 Oct 2020 23:38:53 |
| | System | 24 Oct 2020 23:38:53 |

US3712094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:25:14

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-24T19:38:48', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'dd148bd6-d5bf-4e2c-b2dd-8e025c87b1e3' User entered 'None (1)' | System | 24 Oct 2020 23:38:53 |
| | System | 24 Oct 2020 23:38:53 |

US3712094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:25:14

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-24T19:38:52', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'dd148bd6-d5bf-4e2c-b2dd-8e025c87b1e3' User entered '24 Oct 2020 19:38' | System | 24 Oct 2020 23:38:53 |
| | System | 24 Oct 2020 23:38:53 |

US3712094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:25:14

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| User entered '24 Oct 2020 12:00' | System | 19 Oct 2020 15:22:10 |

US3712094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:25:14

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| User entered '25 Oct 2020 11:59' | System | 19 Oct 2020 15:22:10 |

US3712094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| Data entry locked. | System | 19 Oct 2020 15:22:10 |
| User entered 'Day 7' | System | 19 Oct 2020 15:22:10 |

US3712094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:25:14

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-25T22:07:14', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'ae50236f-7333-401e-b62f-faa6191be8f1' User entered 'None (1)' | System | 26 Oct 2020 02:07:32 |
| | System | 26 Oct 2020 02:07:32 |

US3712094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:25:14

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-25T22:07:18', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'ae50236f-7333-401e-b62f-faa6191be8f1' User entered 'No (N)' | System | 26 Oct 2020 02:07:32 |
| | System | 26 Oct 2020 02:07:32 |

US3712094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-25T22:07:21', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'ae50236f-7333-401e-b62f-faa6191be8f1' User entered 'No (N)' | System | 26 Oct 2020 02:07:32 |
| | System | 26 Oct 2020 02:07:32 |

US3712094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:25:14

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-25T22:07:24', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'ae50236f-7333-401e-b62f-faa6191be8f1' User entered 'None (1)' | System | 26 Oct 2020 02:07:32 |
| | System | 26 Oct 2020 02:07:32 |

US3712094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:25:14

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-25T22:07:29', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'ae50236f-7333-401e-b62f-faa6191be8f1' User entered '25 Oct 2020 22:07' | System | 26 Oct 2020 02:07:32 |
| | System | 26 Oct 2020 02:07:32 |

US3712094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:25:14

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| User entered '25 Oct 2020 12:00' | System | 19 Oct 2020 15:22:10 |

US3712094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:25:14

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| User entered '26 Oct 2020 11:59' | System | 19 Oct 2020 15:22:10 |

US3712094

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| Data entry locked. | System | 19 Oct 2020 15:22:10 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 19 Oct 2020 15:22:10 |

US3712094

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:25:14

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-19T11:47:17', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'dc4d08f1-08d3-467d-b8cc-40096dd1a707' User entered 'None (0)' | System | 19 Oct 2020 15:47:38 |
| | System | 19 Oct 2020 15:47:38 |

US3712094

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:25:14

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-19T11:47:20', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'dc4d08f1-08d3-467d-b8cc-40096dd1a707' User entered 'None (0)' | System | 19 Oct 2020 15:47:38 |
| | System | 19 Oct 2020 15:47:38 |

US3712094

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:25:14

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-19T11:47:21', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'dc4d08f1-08d3-467d-b8cc-40096dd1a707' User entered 'None (0)' | System | 19 Oct 2020 15:47:38 |
| | System | 19 Oct 2020 15:47:38 |

US3712094

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:25:14

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-19T11:47:23', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'dc4d08f1-08d3-467d-b8cc-40096dd1a707' User entered 'None (0)' | System | 19 Oct 2020 15:47:38 |
| | System | 19 Oct 2020 15:47:38 |

US3712094

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:25:14

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-19T11:47:25', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'dc4d08f1-08d3-467d-b8cc-40096dd1a707' User entered 'None (0)' | System | 19 Oct 2020 15:47:38 |
| | System | 19 Oct 2020 15:47:38 |

US3712094

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:25:14

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-19T11:47:27', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'dc4d08f1-08d3-467d-b8cc-40096dd1a707' User entered 'None (0)' | System | 19 Oct 2020 15:47:38 |
| | System | 19 Oct 2020 15:47:38 |

US3712094

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:25:14

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) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-19T11:47:30', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'dc4d08f1-08d3-467d-b8cc-40096dd1a707' User entered 'No (N)' | System | 19 Oct 2020 15:47:38 |
| | System | 19 Oct 2020 15:47:38 |

US3712094

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:25:14

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-19T11:47:34', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'dc4d08f1-08d3-467d-b8cc-40096dd1a707' User entered '19 Oct 2020 11:47' | System | 19 Oct 2020 15:47:38 |
| | System | 19 Oct 2020 15:47:38 |

US3712094

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:25:14

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| User entered '19 Oct 2020 11:36' | System | 19 Oct 2020 15:22:10 |

US3712094

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:25:14

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| User entered '19 Oct 2020 14:06' | System | 19 Oct 2020 15:22:10 |

US3712094

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| Data entry locked. | System | 19 Oct 2020 15:22:10 |
| User entered 'Day 1, after vaccination (at home)' | System | 19 Oct 2020 15:22:10 |

US3712094

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:25:14

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-19T22:18:03', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '0ed6e186-c7b3-4682-a29b-3300f87f145b' User entered 'None (0)' | System | 20 Oct 2020 02:18:24 |
| | System | 20 Oct 2020 02:18:24 |

US3712094

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:25:14

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-19T22:18:05', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '0ed6e186-c7b3-4682-a29b-3300f87f145b' User entered 'None (0)' | System | 20 Oct 2020 02:18:24 |
| | System | 20 Oct 2020 02:18:24 |

US3712094

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:25:14

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-19T22:18:07', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '0ed6e186-c7b3-4682-a29b-3300f87f145b' User entered 'None (0)' | System | 20 Oct 2020 02:18:24 |
| | System | 20 Oct 2020 02:18:24 |

US3712094

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:25:14

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-19T22:18:09', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '0ed6e186-c7b3-4682-a29b-3300f87f145b' User entered 'None (0)' | System | 20 Oct 2020 02:18:24 |
| | System | 20 Oct 2020 02:18:24 |

US3712094

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:25:14

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-19T22:18:11', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '0ed6e186-c7b3-4682-a29b-3300f87f145b' User entered 'None (0)' | System | 20 Oct 2020 02:18:24 |
| | System | 20 Oct 2020 02:18:24 |

US3712094

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:25:14

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-19T22:18:12', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '0ed6e186-c7b3-4682-a29b-3300f87f145b' User entered 'None (0)' | System | 20 Oct 2020 02:18:24 |
| | System | 20 Oct 2020 02:18:24 |

US3712094

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:25:14

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) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-19T22:18:15', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '0ed6e186-c7b3-4682-a29b-3300f87f145b' User entered 'No (N)' | System | 20 Oct 2020 02:18:24 |
| | System | 20 Oct 2020 02:18:24 |

US3712094

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:25:14

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-19T22:18:18', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '0ed6e186-c7b3-4682-a29b-3300f87f145b' User entered '19 Oct 2020 22:18' | System | 20 Oct 2020 02:18:24 |
| | System | 20 Oct 2020 02:18:24 |

US3712094

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:25:14

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| User entered '19 Oct 2020 15:01' | System | 19 Oct 2020 15:22:10 |

US3712094

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:25:14

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| User entered '20 Oct 2020 11:59' | System | 19 Oct 2020 15:22:10 |

US3712094

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| Data entry locked. | System | 19 Oct 2020 15:22:10 |
| User entered 'Day 2' | System | 19 Oct 2020 15:22:10 |

US3712094

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:25:14

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-20T21:11:38', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '3f6598d5-30c2-450d-a5c9-a609d2a49077' User entered 'None (0)' | System | 21 Oct 2020 01:12:20 |
| | System | 21 Oct 2020 01:12:20 |

US3712094

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:25:14

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-20T21:11:43', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '3f6598d5-30c2-450d-a5c9-a609d2a49077' | System | 21 Oct 2020 01:12:20 |
| User entered 'No interference with activity (1)' | System | 21 Oct 2020 01:12:20 |

US3712094

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:25:14

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-20T21:11:45', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '3f6598d5-30c2-450d-a5c9-a609d2a49077' User entered 'None (0)' | System | 21 Oct 2020 01:12:20 |
| | System | 21 Oct 2020 01:12:20 |

US3712094

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:25:14

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-20T21:11:47', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '3f6598d5-30c2-450d-a5c9-a609d2a49077' User entered 'None (0)' | System | 21 Oct 2020 01:12:20 |
| | System | 21 Oct 2020 01:12:20 |

US3712094

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:25:14

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-20T21:11:49', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '3f6598d5-30c2-450d-a5c9-a609d2a49077' User entered 'None (0)' | System | 21 Oct 2020 01:12:20 |
| | System | 21 Oct 2020 01:12:20 |

US3712094

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:25:14

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-20T21:11:50', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '3f6598d5-30c2-450d-a5c9-a609d2a49077' User entered 'None (0)' | System | 21 Oct 2020 01:12:20 |
| | System | 21 Oct 2020 01:12:20 |

US3712094

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:25:14

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) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-20T21:12:08', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '3f6598d5-30c2-450d-a5c9-a609d2a49077' User entered 'No (N)' | System | 21 Oct 2020 01:12:20 |
| | System | 21 Oct 2020 01:12:20 |

US3712094

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:25:14

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-20T21:12:16', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '3f6598d5-30c2-450d-a5c9-a609d2a49077' User entered '20 Oct 2020 21:12' | System | 21 Oct 2020 01:12:20 |
| | System | 21 Oct 2020 01:12:20 |

US3712094

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:25:14

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| User entered '20 Oct 2020 12:00' | System | 19 Oct 2020 15:22:10 |

US3712094

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:25:14

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| User entered '21 Oct 2020 11:59' | System | 19 Oct 2020 15:22:10 |

US3712094

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| Data entry locked. | System | 19 Oct 2020 15:22:10 |
| User entered 'Day 3' | System | 19 Oct 2020 15:22:10 |

US3712094

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:25:14

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-21T17:28:44', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'ae698a95-f242-4879-927f-9b6e67896e13' User entered 'None (0)' | System | 21 Oct 2020 21:29:05 |
| | System | 21 Oct 2020 21:29:05 |

US3712094

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:25:14

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-21T17:28:46', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'ae698a95-f242-4879-927f-9b6e67896e13' User entered 'None (0)' | System | 21 Oct 2020 21:29:05 |
| | System | 21 Oct 2020 21:29:05 |

US3712094

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:25:14

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-21T17:28:48', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'ae698a95-f242-4879-927f-9b6e67896e13' User entered 'None (0)' | System | 21 Oct 2020 21:29:05 |
| | System | 21 Oct 2020 21:29:05 |

US3712094

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:25:14

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-21T17:28:50', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'ae698a95-f242-4879-927f-9b6e67896e13' User entered 'None (0)' | System | 21 Oct 2020 21:29:05 |
| | System | 21 Oct 2020 21:29:05 |

US3712094

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:25:14

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-21T17:28:52', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'ae698a95-f242-4879-927f-9b6e67896e13' User entered 'None (0)' | System | 21 Oct 2020 21:29:05 |
| | System | 21 Oct 2020 21:29:05 |

US3712094

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:25:14

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-21T17:28:54', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'ae698a95-f242-4879-927f-9b6e67896e13' User entered 'None (0)' | System | 21 Oct 2020 21:29:05 |
| | System | 21 Oct 2020 21:29:05 |

US3712094

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:25:14

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) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-21T17:28:58', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'ae698a95-f242-4879-927f-9b6e67896e13' User entered 'No (N)' | System | 21 Oct 2020 21:29:05 |
| | System | 21 Oct 2020 21:29:05 |

US3712094

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:25:14

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-21T17:29:02', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'ae698a95-f242-4879-927f-9b6e67896e13' User entered '21 Oct 2020 17:29' | System | 21 Oct 2020 21:29:05 |
| | System | 21 Oct 2020 21:29:05 |

US3712094

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:25:14

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| User entered '21 Oct 2020 12:00' | System | 19 Oct 2020 15:22:10 |

US3712094

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:25:14

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| User entered '22 Oct 2020 11:59' | System | 19 Oct 2020 15:22:10 |

US3712094

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| Data entry locked. | System | 19 Oct 2020 15:22:10 |
| User entered 'Day 4' | System | 19 Oct 2020 15:22:10 |

US3712094

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:25:14

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-22T20:29:18', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '39a076e5-faec-46e1-8ca0-ceed15f00ec7' User entered 'None (0)' | System | 23 Oct 2020 00:29:37 |
| | System | 23 Oct 2020 00:29:37 |

US3712094

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:25:14

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-22T20:29:20', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '39a076e5-faec-46e1-8ca0-ceed15f00ec7' User entered 'None (0)' | System | 23 Oct 2020 00:29:37 |
| | System | 23 Oct 2020 00:29:37 |

US3712094

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:25:14

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-22T20:29:22', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '39a076e5-faec-46e1-8ca0-ceed15f00ec7' User entered 'None (0)' | System | 23 Oct 2020 00:29:37 |
| | System | 23 Oct 2020 00:29:37 |

US3712094

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:25:14

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-22T20:29:24', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '39a076e5-faec-46e1-8ca0-ceed15f00ec7' User entered 'None (0)' | System | 23 Oct 2020 00:29:37 |
| | System | 23 Oct 2020 00:29:37 |

US3712094

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:25:14

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-22T20:29:25', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '39a076e5-faec-46e1-8ca0-ceed15f00ec7' User entered 'None (0)' | System | 23 Oct 2020 00:29:37 |
| | System | 23 Oct 2020 00:29:37 |

US3712094

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:25:14

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-22T20:29:27', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '39a076e5-faec-46e1-8ca0-ceed15f00ec7' User entered 'None (0)' | System | 23 Oct 2020 00:29:37 |
| | System | 23 Oct 2020 00:29:37 |

US3712094

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:25:14

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) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-22T20:29:28', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '39a076e5-faec-46e1-8ca0-ceed15f00ec7' User entered 'No (N)' | System | 23 Oct 2020 00:29:37 |
| | System | 23 Oct 2020 00:29:37 |

US3712094

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:25:14

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-22T20:29:33', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '39a076e5-faec-46e1-8ca0-ceed15f00ec7' User entered '22 Oct 2020 20:29' | System | 23 Oct 2020 00:29:37 |
| | System | 23 Oct 2020 00:29:37 |

US3712094

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:25:14

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| User entered '22 Oct 2020 12:00' | System | 19 Oct 2020 15:22:10 |

US3712094

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:25:14

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| User entered '23 Oct 2020 11:59' | System | 19 Oct 2020 15:22:10 |

US3712094

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| Data entry locked. | System | 19 Oct 2020 15:22:10 |
| User entered 'Day 5' | System | 19 Oct 2020 15:22:10 |

US3712094

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:25:14

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-23T18:19:57', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '96710891-2869-499a-aa79-03b1145984ba' User entered 'None (0)' | System | 23 Oct 2020 22:20:18 |
| | System | 23 Oct 2020 22:20:18 |

US3712094

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:25:14

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-23T18:19:59', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '96710891-2869-499a-aa79-03b1145984ba' User entered 'None (0)' | System | 23 Oct 2020 22:20:18 |
| | System | 23 Oct 2020 22:20:18 |

US3712094

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:25:14

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-23T18:20:01', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '96710891-2869-499a-aa79-03b1145984ba' User entered 'None (0)' | System | 23 Oct 2020 22:20:18 |
| | System | 23 Oct 2020 22:20:18 |

US3712094

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:25:14

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-23T18:20:03', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '96710891-2869-499a-aa79-03b1145984ba' User entered 'None (0)' | System | 23 Oct 2020 22:20:18 |
| | System | 23 Oct 2020 22:20:18 |

US3712094

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:25:14

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-23T18:20:04', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '96710891-2869-499a-aa79-03b1145984ba' User entered 'None (0)' | System | 23 Oct 2020 22:20:18 |
| | System | 23 Oct 2020 22:20:18 |

US3712094

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:25:14

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-23T18:20:06', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '96710891-2869-499a-aa79-03b1145984ba' User entered 'None (0)' | System | 23 Oct 2020 22:20:18 |
| | System | 23 Oct 2020 22:20:18 |

US3712094

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:25:14

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) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-23T18:20:08', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '96710891-2869-499a-aa79-03b1145984ba' User entered 'No (N)' | System | 23 Oct 2020 22:20:18 |
| | System | 23 Oct 2020 22:20:18 |

US3712094

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:25:14

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-23T18:20:12', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '96710891-2869-499a-aa79-03b1145984ba' User entered '23 Oct 2020 18:20' | System | 23 Oct 2020 22:20:18 |
| | System | 23 Oct 2020 22:20:18 |

US3712094

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:25:14

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| User entered '23 Oct 2020 12:00' | System | 19 Oct 2020 15:22:10 |

US3712094

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:25:14

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| User entered '24 Oct 2020 11:59' | System | 19 Oct 2020 15:22:10 |

US3712094

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| Data entry locked. | System | 19 Oct 2020 15:22:10 |
| User entered 'Day 6' | System | 19 Oct 2020 15:22:10 |

US3712094

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:25:14

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-24T19:38:56', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'a9190166-d3c2-4e56-a43b-9979caf058df' User entered 'None (0)' | System | 24 Oct 2020 23:39:12 |
| | System | 24 Oct 2020 23:39:12 |

US3712094

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:25:14

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-24T19:38:57', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'a9190166-d3c2-4e56-a43b-9979caf058df' User entered 'None (0)' | System | 24 Oct 2020 23:39:12 |
| | System | 24 Oct 2020 23:39:12 |

US3712094

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:25:14

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-24T19:38:59', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'a9190166-d3c2-4e56-a43b-9979caf058df' User entered 'None (0)' | System | 24 Oct 2020 23:39:12 |
| | System | 24 Oct 2020 23:39:12 |

US3712094

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:25:14

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-24T19:39:00', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'a9190166-d3c2-4e56-a43b-9979caf058df' User entered 'None (0)' | System | 24 Oct 2020 23:39:12 |
| | System | 24 Oct 2020 23:39:12 |

US3712094

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:25:14

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-24T19:39:03', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'a9190166-d3c2-4e56-a43b-9979caf058df' User entered 'None (0)' | System | 24 Oct 2020 23:39:12 |
| | System | 24 Oct 2020 23:39:12 |

US3712094

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:25:14

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-24T19:39:04', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'a9190166-d3c2-4e56-a43b-9979caf058df' User entered 'None (0)' | System | 24 Oct 2020 23:39:12 |
| | System | 24 Oct 2020 23:39:12 |

US3712094

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:25:14

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) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-24T19:39:07', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'a9190166-d3c2-4e56-a43b-9979caf058df' User entered 'No (N)' | System | 24 Oct 2020 23:39:12 |
| | System | 24 Oct 2020 23:39:12 |

US3712094

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:25:14

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-24T19:39:11', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'a9190166-d3c2-4e56-a43b-9979caf058df' User entered '24 Oct 2020 19:39' | System | 24 Oct 2020 23:39:12 |
| | System | 24 Oct 2020 23:39:12 |

US3712094

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:25:14

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| User entered '24 Oct 2020 12:00' | System | 19 Oct 2020 15:22:10 |

US3712094

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:25:14

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| User entered '25 Oct 2020 11:59' | System | 19 Oct 2020 15:22:10 |

US3712094

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| Data entry locked. | System | 19 Oct 2020 15:22:10 |
| User entered 'Day 7' | System | 19 Oct 2020 15:22:10 |

US3712094

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:25:14

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-25T22:07:34', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'a0855b3a-2052-46d3-a3a4-bd65771bab11' User entered 'None (0)' | System | 26 Oct 2020 02:08:02 |
| | System | 26 Oct 2020 02:08:02 |

US3712094

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:25:14

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-25T22:07:37', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'a0855b3a-2052-46d3-a3a4-bd65771bab11' User entered 'None (0)' | System | 26 Oct 2020 02:08:02 |
| | System | 26 Oct 2020 02:08:02 |

US3712094

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:25:14

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-25T22:07:41', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'a0855b3a-2052-46d3-a3a4-bd65771bab11' User entered 'None (0)' | System | 26 Oct 2020 02:08:02 |
| | System | 26 Oct 2020 02:08:02 |

US3712094

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:25:14

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-25T22:07:44', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'a0855b3a-2052-46d3-a3a4-bd65771bab11' User entered 'None (0)' | System | 26 Oct 2020 02:08:02 |
| | System | 26 Oct 2020 02:08:02 |

US3712094

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:25:14

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-25T22:07:48', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'a0855b3a-2052-46d3-a3a4-bd65771bab11' User entered 'None (0)' | System | 26 Oct 2020 02:08:02 |
| | System | 26 Oct 2020 02:08:02 |

US3712094

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:25:14

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-25T22:07:51', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'a0855b3a-2052-46d3-a3a4-bd65771bab11' User entered 'None (0)' | System | 26 Oct 2020 02:08:02 |
| | System | 26 Oct 2020 02:08:02 |

US3712094

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:25:14

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) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-25T22:07:53', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'a0855b3a-2052-46d3-a3a4-bd65771bab11' User entered 'No (N)' | System | 26 Oct 2020 02:08:02 |
| | System | 26 Oct 2020 02:08:02 |

US3712094

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:25:14

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-10-25T22:07:58', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'a0855b3a-2052-46d3-a3a4-bd65771bab11' User entered '25 Oct 2020 22:07' | System | 26 Oct 2020 02:08:02 |
| | System | 26 Oct 2020 02:08:02 |

US3712094

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:25:14

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| User entered '25 Oct 2020 12:00' | System | 19 Oct 2020 15:22:10 |

US3712094

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:25:14

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:25:08 |
| User entered '26 Oct 2020 11:59' | System | 19 Oct 2020 15:22:10 |

US3712094

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:25:14

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 21:47:14 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:45:15 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:20:50 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 01 Nov 2020 20:40:25 |

US3712094

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:25:14

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 21:47:14 |
| User signature succeeded. | William Smith (b) (4) | 18 Apr 2021 23:29:00 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 14 Apr 2021 19:24:01 |
| User closed query 'Source seems to note that contact was made on 27Oct2020. If confirmed, please update.' (Site from CRA). | (b) (4), (b) (6) | 14 Apr 2021 19:23:46 |
| Query 'Source seems to note that contact was made on 27Oct2020. If confirmed, please update.' answered with 'updated' (Site from CRA). | (b) (4), (b) (6) | 19 Mar 2021 13:40:58 |
| Signature has been broken. | (b) (4), (b) (6) | 19 Mar 2021 13:40:53 |
| User entered '27 Oct 2020' reason for change: Data Entry Error | (b) (4), (b) (6) | 19 Mar 2021 13:40:53 |
| User opened query 'Source seems to note that contact was made on 27Oct2020. If confirmed, please update.' (Site from CRA). | (b) (4), (b) (6) | 25 Feb 2021 15:46:20 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 25 Feb 2021 15:45:58 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:45:15 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:20:50 |
| User entered '26 Oct 2020' | (b) (4) (b) (4), (b) (6) | 01 Nov 2020 20:40:25 |

US3712094

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:25:14

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 21:47:14 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:45:15 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:20:50 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) (b) (4), (b) (6) | 01 Nov 2020 20:40:25 |

US3712094

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:25:14

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 21:47:14 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:45:15 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:20:50 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 01 Nov 2020 20:40:25 |

US3712094

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:25:14

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 21:47:14 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:45:24 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:20:50 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 01 Nov 2020 20:40:29 |

US3712094

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:25:14

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 21:47:14 |
| User entered 'I' | System | 01 Nov 2020 20:40:29 |

US3712094

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:25:14

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 21:47:14 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:55:26 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:20:50 |
| User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 16Nov2020 is reported under Visit 3 Day 57 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 22 Jan 2021 10:01:47 |
| User closed query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an Immunogenicity Assessment sample collected on 30DEC2020 for the Participant Decision Visit, however, there is no data recorded for the Participant Decision Visit. Please clarify and update as appropriate.' (Site from DM). | (b) (4), (b) (6) | 22 Jan 2021 10:01:29 |
| Query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an Immunogenicity Assessment sample collected on 30DEC2020 for the Participant Decision Visit, however, there is no data recorded for the Participant Decision Visit. Please clarify and update as appropriate.' answered with 'updating' (Site from DM). | (b) (4), (b) (6) | 21 Jan 2021 16:19:59 |
| Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 16Nov2020 is reported under Visit 3 Day 57 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' answered with 'updating' (Site from DM). | (b) (4), (b) (6) | 21 Jan 2021 16:19:51 |
| User opened query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an Immunogenicity Assessment sample collected on 30DEC2020 for the Participant Decision Visit, however, there is no data recorded for the Participant Decision Visit. Please clarify and update as appropriate.' (Site from DM). | (b) (4), (b) (6) | 13 Jan 2021 16:13:56 |

US3712094

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:25:14

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 16Nov2020 is reported under Visit 3 Day 57 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM). User entered 'Yes (Y)' | (b) (4), (b) (6) | 04 Dec 2020 13:29:42 |
| | (b) (4), (b) (6) | 04 Nov 2020 18:59:49 |

US3712094

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:25:14

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 21:47:14 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:55:26 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:20:50 |
| User entered '02 Nov 2020' | (b) (4) (b) (4), (b) (6) | 04 Nov 2020 18:59:49 |

US3712094

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:25:14

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 21:47:14 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:55:26 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:20:50 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) (b) (4), (b) (6) | 04 Nov 2020 18:59:49 |

US3712094

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:25:14

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 21:47:14 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:55:26 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:20:50 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 04 Nov 2020 18:59:49 |

US3712094

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:25:14

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 21:47:14 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 15:55:31 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:20:50 |
| User closed query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Sample dated 30DEC2020 is reported under OL-D1 visit in PPD Central lab, however the same is missing in EDC under Participant Decision Visit OL-D1(1)/ Central Lab Nasopharyngeal Swab(Single) .Please review if the sample has been collected and then update the details under appropriate visit. Else clarify, thank you. | (b) (4) (b) (4), (b) (6) | 22 Jan 2021 10:16:48 |
| ' (Site from DM). | | |
| Query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Sample dated 30DEC2020 is reported under OL-D1 visit in PPD Central lab, however the same is missing in EDC under Participant Decision Visit OL-D1(1)/ Central Lab Nasopharyngeal Swab(Single) .Please review if the sample has been collected and then update the details under appropriate visit. Else clarify, thank you. | (b) (4), (b) (6) | 21 Jan 2021 16:29:25 |
| ' answered with 'updating ' (Site from DM). | | |
| User opened query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Sample dated 30DEC2020 is reported under OL-D1 visit in PPD Central lab, however the same is missing in EDC under Participant Decision Visit OL-D1(1)/ Central Lab Nasopharyngeal Swab(Single) .Please review if the sample has been collected and then update the details under appropriate visit. Else clarify, thank you. | (b) (4), (b) (6) | 06 Jan 2021 06:36:40 |
| ' (Site from DM). | | |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 04 Nov 2020 18:59:51 |

US3712094

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:25:14

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 21:47:14 |
| User entered 'I' | System | 04 Nov 2020 18:59:51 |

US3712094

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:25:14

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 21:47:14 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 16:03:14 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:20:50 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 21 Jan 2021 16:20:10 |

US3712094

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:25:14

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 21:47:14 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 16:03:14 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:20:50 |
| User entered '09 Nov 2020' | (b) (4) (b) (4), (b) (6) | 21 Jan 2021 16:20:10 |

US3712094

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:25:14

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 21:47:14 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 16:03:14 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:20:50 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) (b) (4), (b) (6) | 21 Jan 2021 16:20:10 |

US3712094

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:25:14

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 21:47:14 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 16:03:14 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:20:50 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Jan 2021 16:20:10 |

US3712094

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:25:14

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 21:47:14 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 16:04:30 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:20:50 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 21 Jan 2021 16:20:35 |

US3712094

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:25:14

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 21:47:14 |
| User entered 'I' | System | 21 Jan 2021 16:20:35 |

US3712094

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:25:14

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 21:47:14 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 16:09:14 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 21 Jan 2021 16:20:44 |

US3712094

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 21:47:14 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 16:09:14 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| User entered '16 Nov 2020' | (b) (4) (b) (4), (b) (6) | 21 Jan 2021 16:20:44 |

US3712094

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:25:14

[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 21:47:14 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 16:09:14 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| User entered 'Clinic (Clinic)' | (b) (4) (b) (4), (b) (6) | 21 Jan 2021 16:20:44 |

US3712094

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:25:14

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 21:47:14 |
| User entered 'VISIT3' | System | 21 Jan 2021 16:20:44 |

US3712094

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:25:14

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 21:47:14 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 16:10:26 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 21 Jan 2021 16:22:32 |

US3712094

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:25:14

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 21:47:14 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 16:10:26 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Jan 2021 16:22:32 |

US3712094

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 21:47:14 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 16:10:26 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Jan 2021 16:22:32 |

US3712094

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 21:47:14 |
| User entered empty. | System | 21 Jan 2021 16:22:32 |

US3712094

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 21:47:14 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 16:10:26 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Jan 2021 16:22:32 |

US3712094

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:25:14

[Route of measurement](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 21:47:14 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 16:10:26 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Jan 2021 16:22:32 |

US3712094

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:25:14

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 21:47:14 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 16:10:26 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Jan 2021 16:22:32 |

US3712094

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:25:14

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 21:47:14 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 16:10:26 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Jan 2021 16:22:32 |

US3712094

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:25:14

[Pulse units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 21:47:14 |
| User entered empty. | System | 21 Jan 2021 16:22:32 |

US3712094

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 21:47:14 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 16:10:26 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Jan 2021 16:22:32 |

US3712094

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:25:14

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 21:47:14 |
| User entered empty. | System | 21 Jan 2021 16:22:32 |

US3712094

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 21:47:14 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 16:10:26 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Jan 2021 16:22:32 |

US3712094

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:25:14

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 21:47:14 |
| User entered empty. | System | 21 Jan 2021 16:22:32 |

US3712094

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 21:47:14 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 16:10:26 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Jan 2021 16:22:32 |

US3712094

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:25:14

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 21:47:14 |
| User entered empty. | System | 21 Jan 2021 16:22:32 |

US3712094

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:25:14

[Height \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 21:47:14 |

US3712094

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:25:14

[Weight \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 21:47:14 |

US3712094

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:25:14

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 21:47:14 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 16:13:50 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 21 Jan 2021 16:22:38 |

US3712094

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:25:14

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 21:47:14 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 16:13:50 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Jan 2021 16:22:38 |

US3712094

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:25:14

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 21:47:14 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 16:14:03 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 21 Jan 2021 16:22:45 |

US3712094

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 21:47:14 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 16:14:03 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| User entered '16 Nov 2020' | (b) (4) (b) (4), (b) (6) | 21 Jan 2021 16:22:45 |

US3712094

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:25:14

[Collection time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 21:47:14 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 16:14:03 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| User entered '11:15' | (b) (4) (b) (4), (b) (6) | 21 Jan 2021 16:22:45 |

US3712094

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 21:47:14 |
| User entered '16 Nov 2020 11:15' | System | 21 Jan 2021 16:22:45 |

US3712094

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:25:14

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 21:47:14 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 16:14:29 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 00:21:47 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 21 Jan 2021 16:22:47 |

US3712094

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:25:14

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 21:47:14 |
| User entered 'I' | System | 21 Jan 2021 16:22:47 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered 'Day 61' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '18 Nov 2020 00:01' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '22 Nov 2020 23:59' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered 'Day 68' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[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 (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-11-28T17:59:13', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '310fb8fa-a10c-49ab-9086-508b2f47a827' | System | 28 Nov 2020 22:59:33 |
| User entered 'No (N)' | System | 28 Nov 2020 22:59:33 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Have you been exposed to someone with 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 (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-11-28T17:59:25', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '310fb8fa-a10c-49ab-9086-508b2f47a827' | System | 28 Nov 2020 22:59:33 |
| User entered 'No (N)' | System | 28 Nov 2020 22:59:33 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-11-28T17:59:29', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '310fb8fa-a10c-49ab-9086-508b2f47a827' User entered '28 Nov 2020 17:59:29' | System | 28 Nov 2020 22:59:33 |
| | System | 28 Nov 2020 22:59:33 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '25 Nov 2020 00:01' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '29 Nov 2020 23:59' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered 'Day 75' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[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 (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-12-02T00:01:11', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '0c5cee11-9af5-40b7-90e3-63df2abe7314' | System | 02 Dec 2020 05:01:28 |
| User entered 'No (N)' | System | 02 Dec 2020 05:01:28 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Have you been exposed to someone with 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 (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-12-02T00:01:16', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '0c5cee11-9af5-40b7-90e3-63df2abe7314' | System | 02 Dec 2020 05:01:28 |
| User entered 'No (N)' | System | 02 Dec 2020 05:01:28 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-12-02T00:01:20', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '0c5cee11-9af5-40b7-90e3-63df2abe7314' User entered '02 Dec 2020 00:01:20' | System | 02 Dec 2020 05:01:28 |
| | System | 02 Dec 2020 05:01:28 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '02 Dec 2020 00:01' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '06 Dec 2020 23:59' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered 'Day 82' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[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 (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-12-09T09:54:47', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '76b5e27c-17a4-4e8f-ae0f-57695bca09e3' User entered 'No (N)' | System | 09 Dec 2020 14:55:04 |
| | System | 09 Dec 2020 14:55:04 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Have you been exposed to someone with 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 (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-12-09T09:54:54', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '76b5e27c-17a4-4e8f-ae0f-57695bca09e3' User entered 'No (N)' | System | 09 Dec 2020 14:55:04 |
| | System | 09 Dec 2020 14:55:04 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-12-09T09:54:58', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '76b5e27c-17a4-4e8f-ae0f-57695bca09e3' User entered '09 Dec 2020 09:54:58' | System | 09 Dec 2020 14:55:04 |
| | System | 09 Dec 2020 14:55:04 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '09 Dec 2020 00:01' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '13 Dec 2020 23:59' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered 'Day 89' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[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 (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-12-20T11:59:24', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '6ef2d6ee-f467-42d7-b074-1fd70a692f84' | System | 20 Dec 2020 16:59:32 |
| User entered 'No (N)' | System | 20 Dec 2020 16:59:32 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

Have you been exposed to someone with 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 (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-12-20T11:59:27', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '6ef2d6ee-f467-42d7-b074-1fd70a692f84' | System | 20 Dec 2020 16:59:32 |
| User entered 'No (N)' | System | 20 Dec 2020 16:59:32 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-12-20T11:59:30', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '6ef2d6ee-f467-42d7-b074-1fd70a692f84' User entered '20 Dec 2020 11:59:30' | System | 20 Dec 2020 16:59:32 |
| | System | 20 Dec 2020 16:59:32 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '16 Dec 2020 00:01' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '20 Dec 2020 23:59' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered 'Day 96' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[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 (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-12-23T15:30:06', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '7af17d9a-5306-42e8-b0c1-a1bab2f99eca' User entered 'Yes (Y)' | System | 23 Dec 2020 20:30:37 |
| | System | 23 Dec 2020 20:30:37 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

Have you been exposed to someone with 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 (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-12-23T15:30:11', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '7af17d9a-5306-42e8-b0c1-a1bab2f99eca' User entered 'No (N)' | System | 23 Dec 2020 20:30:37 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-12-23T15:30:14', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '7af17d9a-5306-42e8-b0c1-a1bab2f99eca' User entered 'No (N)' | System | 23 Dec 2020 20:30:37 |
| | System | 23 Dec 2020 20:30:37 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-12-23T15:30:18', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '7af17d9a-5306-42e8-b0c1-a1bab2f99eca' User entered 'Yes (Y)' | System | 23 Dec 2020 20:30:37 |
| | System | 23 Dec 2020 20:30:37 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-12-23T15:30:23', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '7af17d9a-5306-42e8-b0c1-a1bab2f99eca' | System | 23 Dec 2020 20:30:37 |
| User entered 'I confirm I have read this message and will call the study clinic immediately (9)' | System | 23 Dec 2020 20:30:37 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-12-23T15:30:27', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '7af17d9a-5306-42e8-b0c1-a1bab2f99eca' User entered '23 Dec 2020 15:30:27' | System | 23 Dec 2020 20:30:37 |
| | System | 23 Dec 2020 20:30:37 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '23 Dec 2020 00:01' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '27 Dec 2020 23:59' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered 'Day 103' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[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 (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-12-30T14:29:14', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '72cb25f1-6bc1-433c-ba05-8fb8ec37af56' | System | 30 Dec 2020 19:29:23 |
| User entered 'No (N)' | System | 30 Dec 2020 19:29:23 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

Have you been exposed to someone with 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 (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-12-30T14:29:18', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '72cb25f1-6bc1-433c-ba05-8fb8ec37af56' | System | 30 Dec 2020 19:29:23 |
| User entered 'No (N)' | System | 30 Dec 2020 19:29:23 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2020-12-30T14:29:21', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '72cb25f1-6bc1-433c-ba05-8fb8ec37af56' User entered '30 Dec 2020 14:29:21' | System | 30 Dec 2020 19:29:23 |
| | System | 30 Dec 2020 19:29:23 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '30 Dec 2020 00:01' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '03 Jan 2021 23:59' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered 'Day 110' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[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 (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2021-01-08T12:00:27', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '3d5761cc-94df-4008-818f-01dfb504badc' User entered 'No (N)' | System | 08 Jan 2021 17:01:11 |
| | System | 08 Jan 2021 17:01:11 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Have you been exposed to someone with 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 (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2021-01-08T12:00:33', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '3d5761cc-94df-4008-818f-01dfb504badc' | System | 08 Jan 2021 17:01:11 |
| User entered 'No (N)' | System | 08 Jan 2021 17:01:11 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2021-01-08T12:00:44', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '3d5761cc-94df-4008-818f-01dfb504badc' User entered '08 Jan 2021 12:00:44' | System | 08 Jan 2021 17:01:11 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '06 Jan 2021 00:01' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '10 Jan 2021 23:59' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered 'Day 117' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[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 (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2021-01-15T12:17:45', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '62d48298-2aa4-4fbf-a22b-c3c1814c3677' | System | 15 Jan 2021 17:18:15 |
| User entered 'No (N)' | System | 15 Jan 2021 17:18:15 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

Have you been exposed to someone with 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 (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2021-01-15T12:17:48', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '62d48298-2aa4-4fbf-a22b-c3c1814c3677' | System | 15 Jan 2021 17:18:15 |
| User entered 'No (N)' | System | 15 Jan 2021 17:18:15 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2021-01-15T12:17:52', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '62d48298-2aa4-4fbf-a22b-c3c1814c3677' | System | 15 Jan 2021 17:18:15 |
| User entered '15 Jan 2021 12:17:52' | System | 15 Jan 2021 17:18:15 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '13 Jan 2021 00:01' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '17 Jan 2021 23:59' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered 'Day 124' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[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 (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2021-01-22T12:00:23', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'b7feb1db-54bb-44a5-bde4-84799e53f166' | System | 22 Jan 2021 17:00:54 |
| User entered 'No (N)' | System | 22 Jan 2021 17:00:54 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

Have you been exposed to someone with 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 (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2021-01-22T12:00:28', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'b7feb1db-54bb-44a5-bde4-84799e53f166' | System | 22 Jan 2021 17:00:54 |
| User entered 'No (N)' | System | 22 Jan 2021 17:00:54 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2021-01-22T12:00:30', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'b7feb1db-54bb-44a5-bde4-84799e53f166' User entered '22 Jan 2021 12:00:30' | System | 22 Jan 2021 17:00:54 |
| | System | 22 Jan 2021 17:00:54 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '20 Jan 2021 00:01' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '24 Jan 2021 23:59' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered 'Day 131' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[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 (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2021-01-29T00:40:03', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '8097c4df-54da-433a-a2e2-31ede636cc6f' | System | 29 Jan 2021 05:40:19 |
| User entered 'No (N)' | System | 29 Jan 2021 05:40:19 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Have you been exposed to someone with 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 (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2021-01-29T00:40:11', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '8097c4df-54da-433a-a2e2-31ede636cc6f' | System | 29 Jan 2021 05:40:19 |
| User entered 'No (N)' | System | 29 Jan 2021 05:40:19 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2021-01-29T00:40:14', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '8097c4df-54da-433a-a2e2-31ede636cc6f' User entered '29 Jan 2021 00:40:14' | System | 29 Jan 2021 05:40:19 |
| | System | 29 Jan 2021 05:40:19 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '27 Jan 2021 00:01' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '31 Jan 2021 23:59' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered 'Day 138' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[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 (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2021-02-04T13:32:38', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '738904d5-2414-4ddf-a24e-751514aeccc6' | System | 05 Feb 2021 02:19:20 |
| User entered 'No (N)' | System | 05 Feb 2021 02:19:20 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Have you been exposed to someone with 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 (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2021-02-04T13:32:41', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '738904d5-2414-4ddf-a24e-751514aeccc6' | System | 05 Feb 2021 02:19:20 |
| User entered 'No (N)' | System | 05 Feb 2021 02:19:20 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2021-02-04T13:32:44', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '738904d5-2414-4ddf-a24e-751514aeccc6' User entered '04 Feb 2021 13:32:44' | System | 05 Feb 2021 02:19:20 |
| | System | 05 Feb 2021 02:19:20 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '03 Feb 2021 00:01' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '07 Feb 2021 23:59' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered 'Day 145' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[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 (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2021-02-12T12:00:17', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '72de9abc-8221-4d92-9bd1-a5cf7a7bf55a' User entered 'No (N)' | System | 12 Feb 2021 17:01:50 |
| | System | 12 Feb 2021 17:01:50 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

Have you been exposed to someone with 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 (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2021-02-12T12:00:20', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '72de9abc-8221-4d92-9bd1-a5cf7a7bf55a' | System | 12 Feb 2021 17:01:50 |
| User entered 'No (N)' | System | 12 Feb 2021 17:01:50 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2021-02-12T12:00:24', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '72de9abc-8221-4d92-9bd1-a5cf7a7bf55a' User entered '12 Feb 2021 12:00:24' | System | 12 Feb 2021 17:01:50 |
| | System | 12 Feb 2021 17:01:50 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '10 Feb 2021 00:01' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '14 Feb 2021 23:59' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered 'Day 152' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[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 (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2021-02-19T12:03:59', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '389aa41a-4ac9-49a8-b4f3-5d35b3e5f27a' User entered 'No (N)' | System | 19 Feb 2021 17:11:36 |
| | System | 19 Feb 2021 17:11:36 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

Have you been exposed to someone with 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 (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2021-02-19T12:04:01', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '389aa41a-4ac9-49a8-b4f3-5d35b3e5f27a' User entered 'No (N)' | System | 19 Feb 2021 17:11:36 |
| | System | 19 Feb 2021 17:11:36 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2021-02-19T12:04:03', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '389aa41a-4ac9-49a8-b4f3-5d35b3e5f27a' User entered '19 Feb 2021 12:04:03' | System | 19 Feb 2021 17:11:36 |
| | System | 19 Feb 2021 17:11:36 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '17 Feb 2021 00:01' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '21 Feb 2021 23:59' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered 'Day 159' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[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 (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2021-02-28T12:59:07-05:00', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '97fd99dc-662c-438e-87dd-8b3bf77edd92' User entered 'No (N)' | System | 28 Feb 2021 17:59:25 |
| | System | 28 Feb 2021 17:59:25 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

Have you been exposed to someone with 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 (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2021-02-28T12:59:10-05:00', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '97fd99dc-662c-438e-87dd-8b3bf77edd92' | System | 28 Feb 2021 17:59:25 |
| User entered 'No (N)' | System | 28 Feb 2021 17:59:25 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2021-02-28T12:59:13-05:00', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '97fd99dc-662c-438e-87dd-8b3bf77edd92' User entered '28 Feb 2021 12:59:13' | System | 28 Feb 2021 17:59:25 |
| | System | 28 Feb 2021 17:59:25 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '24 Feb 2021 00:01' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '28 Feb 2021 23:59' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered 'Day 166' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[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 (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2021-03-03T00:02:31-05:00', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '036f217c-c034-4b09-995b-a74606cad2d9' User entered 'No (N)' | System | 03 Mar 2021 05:03:58 |
| | System | 03 Mar 2021 05:03:58 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

Have you been exposed to someone with 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 (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2021-03-03T00:02:35-05:00', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '036f217c-c034-4b09-995b-a74606cad2d9' | System | 03 Mar 2021 05:03:58 |
| User entered 'No (N)' | System | 03 Mar 2021 05:03:58 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2021-03-03T00:02:39-05:00', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '036f217c-c034-4b09-995b-a74606cad2d9' User entered '03 Mar 2021 00:02:39' | System | 03 Mar 2021 05:03:58 |
| | System | 03 Mar 2021 05:03:58 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '03 Mar 2021 00:01' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '07 Mar 2021 23:59' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered 'Day 173' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[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 (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2021-03-13T08:29:24-05:00', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '134f55ae-9181-414a-b487-1e39dc175c7a' | System | 13 Mar 2021 13:29:37 |
| User entered 'No (N)' | System | 13 Mar 2021 13:29:37 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Have you been exposed to someone with 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 (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2021-03-13T08:29:27-05:00', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '134f55ae-9181-414a-b487-1e39dc175c7a' | System | 13 Mar 2021 13:29:37 |
| User entered 'No (N)' | System | 13 Mar 2021 13:29:37 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2021-03-13T08:29:33-05:00', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '134f55ae-9181-414a-b487-1e39dc175c7a' User entered '13 Mar 2021 08:29:33' | System | 13 Mar 2021 13:29:37 |
| | System | 13 Mar 2021 13:29:37 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '10 Mar 2021 00:01' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '14 Mar 2021 23:59' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered 'Day 180' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[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 (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2021-03-19T12:32:01-04:00', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '92f00edb-4aa4-4f71-9d84-e53454cd57ef' | System | 19 Mar 2021 16:32:08 |
| User entered 'No (N)' | System | 19 Mar 2021 16:32:08 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

Have you been exposed to someone with 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 (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2021-03-19T12:32:03-04:00', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '92f00edb-4aa4-4f71-9d84-e53454cd57ef' | System | 19 Mar 2021 16:32:08 |
| User entered 'No (N)' | System | 19 Mar 2021 16:32:08 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2021-03-19T12:32:06-04:00', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '92f00edb-4aa4-4f71-9d84-e53454cd57ef' User entered '19 Mar 2021 12:32:06' | System | 19 Mar 2021 16:32:08 |
| | System | 19 Mar 2021 16:32:08 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '17 Mar 2021 00:01' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '21 Mar 2021 23:59' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered 'Day 187' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[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 (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2021-03-24T00:02:13-04:00', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '81344824-2fbe-4c7f-8607-0f4224111553' | System | 24 Mar 2021 04:03:31 |
| User entered 'No (N)' | System | 24 Mar 2021 04:03:31 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

Have you been exposed to someone with 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 (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2021-03-24T00:02:33-04:00', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '81344824-2fbe-4c7f-8607-0f4224111553' | System | 24 Mar 2021 04:03:31 |
| User entered 'No (N)' | System | 24 Mar 2021 04:03:31 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2021-03-24T00:02:35-04:00', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '81344824-2fbe-4c7f-8607-0f4224111553' User entered '24 Mar 2021 00:02:35' | System | 24 Mar 2021 04:03:31 |
| | System | 24 Mar 2021 04:03:31 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '24 Mar 2021 00:01' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '28 Mar 2021 23:59' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered 'Day 194' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[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 (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2021-04-01T11:09:59-04:00', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'ec588ee4-ba81-4a93-bbf6-c3b16ec40892' | System | 01 Apr 2021 15:10:11 |
| User entered 'No (N)' | System | 01 Apr 2021 15:10:11 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Have you been exposed to someone with 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 (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2021-04-01T11:10:01-04:00', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'ec588ee4-ba81-4a93-bbf6-c3b16ec40892' | System | 01 Apr 2021 15:10:11 |
| User entered 'No (N)' | System | 01 Apr 2021 15:10:11 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2021-04-01T11:10:05-04:00', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'ec588ee4-ba81-4a93-bbf6-c3b16ec40892' | System | 01 Apr 2021 15:10:11 |
| User entered '01 Apr 2021 11:10:05' | System | 01 Apr 2021 15:10:11 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '31 Mar 2021 00:01' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '04 Apr 2021 23:59' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered 'Day 201' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[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 (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2021-04-07T15:50:05-04:00', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'fd229f15-d8cb-465f-805c-b7f844538c78' | System | 07 Apr 2021 19:50:12 |
| User entered 'No (N)' | System | 07 Apr 2021 19:50:12 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

Have you been exposed to someone with 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 (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2021-04-07T15:50:07-04:00', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'fd229f15-d8cb-465f-805c-b7f844538c78' | System | 07 Apr 2021 19:50:12 |
| User entered 'No (N)' | System | 07 Apr 2021 19:50:12 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2021-04-07T15:50:10-04:00', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'fd229f15-d8cb-465f-805c-b7f844538c78' | System | 07 Apr 2021 19:50:12 |
| User entered '07 Apr 2021 15:50:10' | System | 07 Apr 2021 19:50:12 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '07 Apr 2021 00:01' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '11 Apr 2021 23:59' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered 'Day 208' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[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 (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2021-04-15T03:13:13-04:00', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'c2f78978-8693-425b-99bb-547a81cd6503' | System | 15 Apr 2021 07:13:21 |
| User entered 'No (N)' | System | 15 Apr 2021 07:13:21 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

Have you been exposed to someone with 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 (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2021-04-15T03:13:16-04:00', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'c2f78978-8693-425b-99bb-547a81cd6503' | System | 15 Apr 2021 07:13:21 |
| User entered 'No (N)' | System | 15 Apr 2021 07:13:21 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2021-04-15T03:13:19-04:00', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'c2f78978-8693-425b-99bb-547a81cd6503' | System | 15 Apr 2021 07:13:21 |
| User entered '15 Apr 2021 03:13:19' | System | 15 Apr 2021 07:13:21 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '14 Apr 2021 00:01' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '18 Apr 2021 23:59' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered 'Day 215' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[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 (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2021-04-23T12:15:35-04:00', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'db40921a-5485-43ac-8f05-2980045ac682' | System | 23 Apr 2021 16:16:36 |
| User entered 'No (N)' | System | 23 Apr 2021 16:16:36 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

Have you been exposed to someone with 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 (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2021-04-23T12:15:37-04:00', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'db40921a-5485-43ac-8f05-2980045ac682' | System | 23 Apr 2021 16:16:36 |
| User entered 'No (N)' | System | 23 Apr 2021 16:16:36 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2021-04-23T12:15:40-04:00', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'db40921a-5485-43ac-8f05-2980045ac682' | System | 23 Apr 2021 16:16:36 |
| User entered '23 Apr 2021 12:15:40' | System | 23 Apr 2021 16:16:36 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '21 Apr 2021 00:01' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '25 Apr 2021 23:59' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered 'Day 222' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[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 (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2021-04-28T00:03:21-04:00', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'b1b7b658-4fb6-40b3-89c0-7daa046dc247' | System | 29 Apr 2021 04:59:57 |
| User entered 'No (N)' | System | 29 Apr 2021 04:59:57 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

Have you been exposed to someone with 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 (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2021-04-28T00:03:23-04:00', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'b1b7b658-4fb6-40b3-89c0-7daa046dc247' | System | 29 Apr 2021 04:59:57 |
| User entered 'No (N)' | System | 29 Apr 2021 04:59:57 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2021-04-28T00:03:26-04:00', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: 'b1b7b658-4fb6-40b3-89c0-7daa046dc247' | System | 29 Apr 2021 04:59:57 |
| User entered '28 Apr 2021 00:03:26' | System | 29 Apr 2021 04:59:57 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '28 Apr 2021 00:01' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '02 May 2021 23:59' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered 'Day 229' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '05 May 2021 00:01' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '09 May 2021 23:59' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered 'Day 236' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '12 May 2021 00:01' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '16 May 2021 23:59' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered 'Day 243' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '19 May 2021 00:01' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '23 May 2021 23:59' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered 'Day 250' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '26 May 2021 00:01' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '30 May 2021 23:59' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered 'Day 257' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '02 Jun 2021 00:01' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '06 Jun 2021 23:59' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered 'Day 264' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '09 Jun 2021 00:01' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '13 Jun 2021 23:59' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered 'Day 271' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '16 Jun 2021 00:01' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '20 Jun 2021 23:59' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered 'Day 278' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '23 Jun 2021 00:01' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '27 Jun 2021 23:59' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered 'Day 285' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '30 Jun 2021 00:01' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '04 Jul 2021 23:59' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered 'Day 292' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '07 Jul 2021 00:01' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '11 Jul 2021 23:59' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered 'Day 299' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '14 Jul 2021 00:01' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '18 Jul 2021 23:59' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered 'Day 306' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '21 Jul 2021 00:01' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '25 Jul 2021 23:59' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered 'Day 313' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '28 Jul 2021 00:01' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '01 Aug 2021 23:59' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered 'Day 320' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '04 Aug 2021 00:01' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '08 Aug 2021 23:59' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered 'Day 327' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '11 Aug 2021 00:01' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '15 Aug 2021 23:59' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered 'Day 334' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '18 Aug 2021 00:01' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '22 Aug 2021 23:59' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered 'Day 341' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '25 Aug 2021 00:01' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '29 Aug 2021 23:59' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered 'Day 348' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '01 Sep 2021 00:01' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '05 Sep 2021 23:59' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered 'Day 355' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '08 Sep 2021 00:01' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '12 Sep 2021 23:59' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered 'Day 362' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '15 Sep 2021 00:01' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '19 Sep 2021 23:59' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered 'Day 369' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '22 Sep 2021 00:01' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '26 Sep 2021 23:59' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered 'Day 376' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '29 Sep 2021 00:01' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '03 Oct 2021 23:59' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered 'Day 383' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '06 Oct 2021 00:01' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '10 Oct 2021 23:59' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered 'Day 390' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '13 Oct 2021 00:01' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '17 Oct 2021 23:59' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered 'Day 397' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '20 Oct 2021 00:01' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '24 Oct 2021 23:59' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered 'Day 404' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '27 Oct 2021 00:01' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '31 Oct 2021 23:59' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered 'Day 411' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '03 Nov 2021 00:01' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '07 Nov 2021 23:59' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered 'Day 418' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '10 Nov 2021 00:01' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '14 Nov 2021 23:59' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered 'Day 425' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '17 Nov 2021 00:01' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '21 Nov 2021 23:59' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered 'Day 432' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '24 Nov 2021 00:01' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '28 Nov 2021 23:59' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered 'Day 439' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '01 Dec 2021 00:01' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '05 Dec 2021 23:59' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered 'Day 446' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '08 Dec 2021 00:01' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '12 Dec 2021 23:59' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered 'Day 453' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '15 Dec 2021 00:01' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '19 Dec 2021 23:59' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered 'Day 460' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '22 Dec 2021 00:01' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '26 Dec 2021 23:59' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered 'Day 467' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '29 Dec 2021 00:01' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '02 Jan 2022 23:59' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered 'Day 474' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '05 Jan 2022 00:01' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '09 Jan 2022 23:59' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered 'Day 481' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '12 Jan 2022 00:01' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '16 Jan 2022 23:59' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered 'Day 488' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '19 Jan 2022 00:01' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '23 Jan 2022 23:59' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered 'Day 495' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '26 Jan 2022 00:01' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '30 Jan 2022 23:59' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered 'Day 502' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '02 Feb 2022 00:01' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '06 Feb 2022 23:59' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered 'Day 509' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '09 Feb 2022 00:01' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '13 Feb 2022 23:59' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered 'Day 516' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '16 Feb 2022 00:01' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '20 Feb 2022 23:59' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered 'Day 523' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '23 Feb 2022 00:01' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '27 Feb 2022 23:59' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered 'Day 530' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '02 Mar 2022 00:01' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '06 Mar 2022 23:59' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered 'Day 537' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '09 Mar 2022 00:01' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '13 Mar 2022 23:59' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered 'Day 544' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '16 Mar 2022 00:01' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '20 Mar 2022 23:59' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered 'Day 551' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '23 Mar 2022 00:01' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '27 Mar 2022 23:59' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered 'Day 558' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '30 Mar 2022 00:01' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '03 Apr 2022 23:59' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered 'Day 565' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '06 Apr 2022 00:01' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '10 Apr 2022 23:59' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered 'Day 572' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '13 Apr 2022 00:01' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '17 Apr 2022 23:59' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered 'Day 579' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '20 Apr 2022 00:01' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '24 Apr 2022 23:59' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered 'Day 586' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '27 Apr 2022 00:01' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '01 May 2022 23:59' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered 'Day 593' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '04 May 2022 00:01' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '08 May 2022 23:59' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered 'Day 600' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '11 May 2022 00:01' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '15 May 2022 23:59' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered 'Day 607' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '18 May 2022 00:01' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '22 May 2022 23:59' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered 'Day 614' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '25 May 2022 00:01' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '29 May 2022 23:59' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered 'Day 621' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '01 Jun 2022 00:01' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '05 Jun 2022 23:59' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered 'Day 628' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '08 Jun 2022 00:01' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '12 Jun 2022 23:59' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered 'Day 635' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '15 Jun 2022 00:01' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '19 Jun 2022 23:59' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered 'Day 642' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '22 Jun 2022 00:01' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '26 Jun 2022 23:59' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered 'Day 649' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '29 Jun 2022 00:01' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '03 Jul 2022 23:59' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered 'Day 656' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '06 Jul 2022 00:01' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '10 Jul 2022 23:59' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered 'Day 663' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '13 Jul 2022 00:01' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '17 Jul 2022 23:59' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered 'Day 670' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '20 Jul 2022 00:01' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '24 Jul 2022 23:59' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered 'Day 677' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '27 Jul 2022 00:01' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '31 Jul 2022 23:59' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered 'Day 684' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '03 Aug 2022 00:01' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '07 Aug 2022 23:59' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered 'Day 691' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '10 Aug 2022 00:01' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '14 Aug 2022 23:59' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered 'Day 698' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '17 Aug 2022 00:01' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '21 Aug 2022 23:59' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered 'Day 705' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '24 Aug 2022 00:01' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '28 Aug 2022 23:59' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered 'Day 712' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '31 Aug 2022 00:01' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '04 Sep 2022 23:59' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered 'Day 719' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '07 Sep 2022 00:01' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '11 Sep 2022 23:59' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered 'Day 726' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '14 Sep 2022 00:01' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '18 Sep 2022 23:59' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered 'Day 733' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '21 Sep 2022 00:01' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '25 Sep 2022 23:59' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered 'Day 740' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '28 Sep 2022 00:01' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '02 Oct 2022 23:59' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered 'Day 747' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '05 Oct 2022 00:01' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '09 Oct 2022 23:59' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered 'Day 754' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '12 Oct 2022 00:01' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '16 Oct 2022 23:59' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered 'Day 761' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '19 Oct 2022 00:01' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '23 Oct 2022 23:59' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered 'Day 768' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '26 Oct 2022 00:01' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '30 Oct 2022 23:59' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered 'Day 775' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '02 Nov 2022 00:01' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '06 Nov 2022 23:59' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered 'Day 782' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '09 Nov 2022 00:01' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '13 Nov 2022 23:59' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered 'Day 789' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '16 Nov 2022 00:01' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '20 Nov 2022 23:59' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered 'Day 796' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '23 Nov 2022 00:01' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:14

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 08:15:13 |
| Amendment Manager: User entered '27 Nov 2022 23:59' | System | 20 Nov 2020 08:15:13 |

US3712094

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:25:14

[Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 22:46:06 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2021-02-28T12:59:19-05:00', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '75968876-609f-4988-8a5c-ca051d6526ff' | System | 28 Feb 2021 17:59:25 |
| User entered 'No (N)' | System | 28 Feb 2021 17:59:25 |

US3712094

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:25:14

[Date & Time of Submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 22:46:06 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A2B1C565-3B7E-4D0B-ADEB-7EFF87F91EFA)', Time: '2021-02-28T12:59:23-05:00', User OID: 'PatientReportedOutcome (US3712094)', ODM File OID: '75968876-609f-4988-8a5c-ca051d6526ff' User entered '28 Feb 2021 12:59:23' | System | 28 Feb 2021 17:59:25 |
| | System | 28 Feb 2021 17:59:25 |

US3712094

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:25:14

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:04:12 |
| User signature succeeded. | William Smith (b) (4) | 10 Mar 2021 02:31:13 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 16:16:31 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 04 Feb 2021 15:43:02 |

US3712094

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:25:14

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:04:12 |
| User signature succeeded. | William Smith (b) (4) | 10 Mar 2021 02:31:13 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 16:16:31 |
| User entered '14 Dec 2020' | (b) (4), (b) (6) | 04 Feb 2021 15:43:02 |

US3712094

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:25:14

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:04:12 |
| User signature succeeded. | William Smith (b) (4) | 10 Mar 2021 02:31:13 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 16:16:31 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4), (b) (6) | 04 Feb 2021 15:43:02 |

US3712094

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:25:14

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:04:12 |
| User signature succeeded. | William Smith (b) (4) | 10 Mar 2021 02:31:13 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 16:16:31 |
| User entered empty. | (b) (4), (b) (6) | 04 Feb 2021 15:43:02 |

US3712094

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:25:14

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:04:12 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:00:12 |
| User signature succeeded. | William Smith (b) (4) | 10 Mar 2021 02:31:13 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 22 Jan 2021 14:36:41 |

US3712094

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:25:14

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 19:04:12 |
| User entered 'I' | System | 22 Jan 2021 14:36:41 |

US3712094

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:25:14

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 05:26:25 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 16:34:38 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 22 Jan 2021 14:36:49 |

US3712094

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:25:14

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 05:26:25 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 16:34:38 |
| User entered '16 Jan 2021' | (b) (4), (b) (6) | 22 Jan 2021 14:36:49 |

US3712094

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:25:14

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 05:26:25 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 16:34:38 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4), (b) (6) | 22 Jan 2021 14:36:49 |

US3712094

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:25:14

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 05:26:25 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 16:34:38 |
| User entered empty. | (b) (4), (b) (6) | 22 Jan 2021 14:36:49 |

US3712094

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:25:14

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 05:26:25 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 16:35:57 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 22 Jan 2021 14:36:51 |

US3712094

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:25:14

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 05:26:25 |
| User entered 'I' | System | 22 Jan 2021 14:36:51 |

US3712094

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:25:14

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 05:26:25 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 16:36:04 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 22 Feb 2021 13:32:32 |

US3712094

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:25:14

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 05:26:25 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 16:36:04 |
| User entered '15 Feb 2021' | (b) (4), (b) (6) | 22 Feb 2021 13:32:32 |

US3712094

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:25:14

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 05:26:25 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 16:36:04 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4), (b) (6) | 22 Feb 2021 13:32:32 |

US3712094

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:25:14

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 05:26:25 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 16:36:04 |
| User entered empty. | (b) (4), (b) (6) | 22 Feb 2021 13:32:32 |

US3712094

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:25:14

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 05:26:25 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 16:41:25 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 22 Feb 2021 13:32:35 |

US3712094

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:25:14

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 05:26:25 |
| User entered 'I' | System | 22 Feb 2021 13:32:35 |

US3712094

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:25:14

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 08:38:28 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 19:26:32 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 19 Mar 2021 13:45:57 |

US3712094

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:25:14

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 08:38:28 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 19:26:32 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered '15 Mar 2021' | (b) (4) (b) (4), (b) (6) | 19 Mar 2021 13:45:57 |

US3712094

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:25:14

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 08:38:28 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 19:26:32 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) (b) (4), (b) (6) | 19 Mar 2021 13:45:57 |

US3712094

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:25:14

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 08:38:28 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 19:26:32 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 19 Mar 2021 13:45:57 |

US3712094

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:25:14

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 08:38:28 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 19:27:08 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 19 Mar 2021 13:45:59 |

US3712094

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:25:14

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 08:38:28 |
| User entered 'I' | System | 19 Mar 2021 13:45:59 |

US3712094

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:25:14

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 23 Apr 2021 21:40:01 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 21 Apr 2021 13:44:34 |

US3712094

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 23 Apr 2021 21:40:01 |
| User entered '19 Apr 2021' | (b) (4) (b) (4), (b) (6) | 21 Apr 2021 13:44:34 |

US3712094

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 23 Apr 2021 21:40:01 |
| User entered 'Clinic (Clinic)' | (b) (4) (b) (4), (b) (6) | 21 Apr 2021 13:44:34 |

US3712094

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:25:14

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|--------|----------------------|
| User entered 'VISIT4' | System | 21 Apr 2021 13:44:34 |

US3712094

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:25:14

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 23 Apr 2021 21:40:01 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 21 Apr 2021 13:44:41 |

US3712094

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:25:14

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 23 Apr 2021 21:40:01 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Apr 2021 13:44:41 |

US3712094

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 23 Apr 2021 21:40:01 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Apr 2021 13:44:41 |

US3712094

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 21 Apr 2021 13:44:41 |

US3712094

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:25:14

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 23 Apr 2021 21:40:01 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Apr 2021 13:44:41 |

US3712094

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:25:14

[Route of measurement](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 23 Apr 2021 21:40:01 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Apr 2021 13:44:41 |

US3712094

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:25:14

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 23 Apr 2021 21:40:01 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Apr 2021 13:44:41 |

US3712094

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:25:14

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 23 Apr 2021 21:40:01 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Apr 2021 13:44:41 |

US3712094

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:25:14

[Pulse units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 21 Apr 2021 13:44:41 |

US3712094

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 23 Apr 2021 21:40:01 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Apr 2021 13:44:41 |

US3712094

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:25:14

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 21 Apr 2021 13:44:41 |

US3712094

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 23 Apr 2021 21:40:01 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Apr 2021 13:44:41 |

US3712094

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:25:14

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 21 Apr 2021 13:44:41 |

US3712094

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 23 Apr 2021 21:40:01 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Apr 2021 13:44:41 |

US3712094

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:25:14

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 21 Apr 2021 13:44:41 |

US3712094

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:25:14

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 23 Apr 2021 21:40:01 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 21 Apr 2021 13:44:44 |

US3712094

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:25:14

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 23 Apr 2021 21:40:01 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Apr 2021 13:44:44 |

US3712094

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:25:14

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 23 Apr 2021 21:40:01 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 21 Apr 2021 13:44:49 |

US3712094

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:25:14

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 23 Apr 2021 21:40:01 |
| User entered '19 Apr 2021' | (b) (4) (b) (4), (b) (6) | 21 Apr 2021 13:44:49 |

US3712094

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:25:14

[Collection time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 23 Apr 2021 21:40:01 |
| User entered '14:49' | (b) (4) (b) (4), (b) (6) | 21 Apr 2021 13:44:49 |

US3712094

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '19 Apr 2021 14:49' | System | 21 Apr 2021 13:44:49 |

US3712094

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:25:14

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 23 Apr 2021 21:40:01 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 21 Apr 2021 13:44:51 |

US3712094

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:25:14

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 21 Apr 2021 13:44:51 |

US3712094

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

Form: Visit Date

Generated On: 10 Jun 2021 09:25:14

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:18:48 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 21 Jan 2021 16:30:08 |

US3712094

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

Form: Visit Date

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:18:48 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered '30 Dec 2020' | (b) (4) (b) (4), (b) (6) | 21 Jan 2021 16:30:08 |

US3712094

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

Form: Visit Date

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:18:48 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered 'Clinic (Clinic)' | (b) (4) (b) (4), (b) (6) | 21 Jan 2021 16:30:08 |

US3712094

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

Form: Visit Date

Generated On: 10 Jun 2021 09:25:14

[Folder OID](#)

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| User entered 'UNBLND_DECIDE' | System | 21 Jan 2021 16:30:08 |

US3712094

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

Form: Unblinding

Generated On: 10 Jun 2021 09:25:14

[Date of updated informed consent \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:23:03 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered '30 Dec 2020' reason for change: Data Entry Error | (b) (4) (b) (4), (b) (6) | 29 Mar 2021 20:00:02 |
| User entered '24 Dec 2020' | (b) (4), (b) (6) | 21 Jan 2021 16:42:13 |

US3712094

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

Form: Unblinding

Generated On: 10 Jun 2021 09:25:14

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered '0' WR# 5295537 | (b) (4) | 10 Mar 2021 16:55:28 |
| Amendment Manager inserted this DataPoint. | System | 06 Mar 2021 08:59:24 |

US3712094

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

Form: Unblinding

Generated On: 10 Jun 2021 09:25:14

[Was the participant unblinded?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:23:03 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 21 Jan 2021 16:42:13 |

US3712094

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

Form: Unblinding

Generated On: 10 Jun 2021 09:25:14

[Under what version of the Protocol was the Participant unblinded?](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537 | (b) (4) | 10 Mar 2021 16:55:28 |
| Amendment Manager inserted this DataPoint. | System | 06 Mar 2021 08:59:24 |

US3712094

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

Form: Unblinding

Generated On: 10 Jun 2021 09:25:14

Date of unblinding (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:23:03 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered '30 Dec 2020' | (b) (4) (b) (4), (b) (6) | 21 Jan 2021 16:42:13 |

US3712094

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

Form: Unblinding

Generated On: 10 Jun 2021 09:25:14

[Participant randomization assignment](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:23:03 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered 'Placebo (Placebo)' | (b) (4) (b) (4), (b) (6) | 21 Jan 2021 16:42:13 |

US3712094

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

Form: Unblinding

Generated On: 10 Jun 2021 09:25:14

[Actual Dose 1](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:23:03 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered 'Placebo (Placebo)' | (b) (4) (b) (4), (b) (6) | 21 Jan 2021 16:42:13 |

US3712094

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

Form: Unblinding

Generated On: 10 Jun 2021 09:25:14

[Actual Dose 2](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:23:03 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered 'Placebo (Placebo)' | (b) (4) (b) (4), (b) (6) | 21 Jan 2021 16:42:13 |

US3712094

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

Form: Unblinding

Generated On: 10 Jun 2021 09:25:14

[Will participant receive mRNA-1273?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:23:03 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 21 Jan 2021 16:42:13 |

US3712094

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

Form: Unblinding

Generated On: 10 Jun 2021 09:25:14

[Placebo Only Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| User entered 'I' | System | 21 Jan 2021 16:42:13 |

US3712094

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

Form: Unblinding

Generated On: 10 Jun 2021 09:25:14

[Continuing with mRNA-1273](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| User entered 'I' | System | 21 Jan 2021 16:42:13 |

US3712094

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:25:14

[Height](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:24:59 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered '168.2' cm | (b) (4) (b) (4), (b) (6) | 21 Jan 2021 16:43:10 |

US3712094

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:25:14

[Weight](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:24:59 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered '67.6' kg | (b) (4) (b) (4), (b) (6) | 21 Jan 2021 16:43:10 |

US3712094

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:25:14

BMI (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| User entered '23.89432' | System | 21 Jan 2021 16:43:10 |
| DataPoint set to visible. | System | 21 Jan 2021 16:42:13 |

US3712094

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:25:14

[Height](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:24:59 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered '168.2' cm | (b) (4) (b) (4), (b) (6) | 21 Jan 2021 16:43:10 |

US3712094

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:25:14

[Weight](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:24:59 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered '67.6' kg | (b) (4) (b) (4), (b) (6) | 21 Jan 2021 16:43:10 |

US3712094

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:25:14

BMI (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| User entered '23.89432' | System | 21 Jan 2021 16:43:10 |
| DataPoint set to visible. | System | 21 Jan 2021 16:42:13 |

US3712094

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:14

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| User accepted default value 'Pre-Dose (PREDOSE)' | (b) (4), (b) (6) | 21 Jan 2021 16:43:10 |

US3712094

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:14

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:24:59 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 21 Jan 2021 16:43:10 |

US3712094

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:14

Date of assessment (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:24:59 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered '30 Dec 2020' | (b) (4) (b) (4), (b) (6) | 21 Jan 2021 16:43:10 |

US3712094

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:14

[Time of assessment \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:24:59 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered '15:00' | (b) (4) (b) (4), (b) (6) | 21 Jan 2021 16:43:10 |

US3712094

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| User entered '30 Dec 2020 15:00' | System | 21 Jan 2021 16:43:10 |

US3712094

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:24:59 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered '36.8' C | (b) (4) (b) (4), (b) (6) | 21 Jan 2021 16:43:10 |

US3712094

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:14

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:24:59 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered 'Oral (Oral)' | (b) (4) (b) (4), (b) (6) | 21 Jan 2021 16:43:10 |

US3712094

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:14

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:24:59 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Jan 2021 16:43:10 |

US3712094

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:14

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:24:59 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered '79' | (b) (4) (b) (4), (b) (6) | 21 Jan 2021 16:43:10 |

US3712094

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:14

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| User entered 'bpm' | System | 21 Jan 2021 16:43:10 |

US3712094

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:24:59 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered '14' | (b) (4) (b) (4), (b) (6) | 21 Jan 2021 16:43:10 |

US3712094

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:14

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| User entered 'breaths/min' | System | 21 Jan 2021 16:43:10 |

US3712094

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:24:59 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered '111' | (b) (4) (b) (4), (b) (6) | 21 Jan 2021 16:43:10 |

US3712094

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:14

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| User entered 'mmHg' | System | 21 Jan 2021 16:43:10 |

US3712094

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:24:59 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered '71' | (b) (4) (b) (4), (b) (6) | 21 Jan 2021 16:43:10 |

US3712094

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:14

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| User entered 'mmHg' | System | 21 Jan 2021 16:43:10 |

US3712094

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:25:14

[Height](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:24:59 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered '168.2' cm | (b) (4) (b) (4), (b) (6) | 21 Jan 2021 16:43:10 |

US3712094

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:25:14

[Weight](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:24:59 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered '67.6' kg | (b) (4) (b) (4), (b) (6) | 21 Jan 2021 16:43:10 |

US3712094

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:25:14

BMI (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| User entered '23.89432' | System | 21 Jan 2021 16:43:10 |
| DataPoint set to visible. | System | 21 Jan 2021 16:42:13 |

US3712094

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:14

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| User accepted default value 'Post-Dose (POSTDOSE)' | (b) (4), (b) (6) | 21 Jan 2021 16:43:10 |

US3712094

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:14

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:24:59 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 21 Jan 2021 16:43:10 |

US3712094

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:14

[Date of assessment \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:24:59 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered '30 Dec 2020' | (b) (4) (b) (4), (b) (6) | 21 Jan 2021 16:43:10 |

US3712094

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:14

[Time of assessment \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:24:59 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered '15:45' | (b) (4) (b) (4), (b) (6) | 21 Jan 2021 16:43:10 |

US3712094

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| User entered '30 Dec 2020 15:45' | System | 21 Jan 2021 16:43:10 |

US3712094

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:24:59 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered '36.9' C | (b) (4) (b) (4), (b) (6) | 21 Jan 2021 16:43:10 |

US3712094

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:14

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:24:59 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered 'Oral (Oral)' | (b) (4) (b) (4), (b) (6) | 21 Jan 2021 16:43:10 |

US3712094

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:14

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:24:59 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Jan 2021 16:43:10 |

US3712094

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:14

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:24:59 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered '77' | (b) (4) (b) (4), (b) (6) | 21 Jan 2021 16:43:10 |

US3712094

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:14

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| User entered 'bpm' | System | 21 Jan 2021 16:43:10 |

US3712094

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:24:59 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered '14' | (b) (4) (b) (4), (b) (6) | 21 Jan 2021 16:43:10 |

US3712094

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:14

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| User entered 'breaths/min' | System | 21 Jan 2021 16:43:10 |

US3712094

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:24:59 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered '105' | (b) (4) (b) (4), (b) (6) | 21 Jan 2021 16:43:10 |

US3712094

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:14

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| User entered 'mmHg' | System | 21 Jan 2021 16:43:10 |

US3712094

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:24:59 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered '72' | (b) (4) (b) (4), (b) (6) | 21 Jan 2021 16:43:10 |

US3712094

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:14

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| User entered 'mmHg' | System | 21 Jan 2021 16:43:10 |

US3712094

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

Form: Physical Examination

Generated On: 10 Jun 2021 09:25:14

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:25:03 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 21 Jan 2021 16:43:53 |

US3712094

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

Form: Physical Examination

Generated On: 10 Jun 2021 09:25:14

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:25:03 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered '30 Dec 2020' | (b) (4) (b) (4), (b) (6) | 21 Jan 2021 16:43:53 |

US3712094

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

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:25:14

[Was the pregnancy test performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:25:12 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 21 Jan 2021 16:42:25 |

US3712094

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

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:25:14

[Date of test \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:25:12 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered '30 Dec 2020' | (b) (4) (b) (4), (b) (6) | 21 Jan 2021 16:42:25 |

US3712094

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

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:25:14

[Test performed](#)

| Audit | User | Time (GMT) |
|------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:25:12 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered 'Urine (URINE)' | (b) (4) (b) (4), (b) (6) | 21 Jan 2021 16:42:25 |

US3712094

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

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:25:14

[Result](#)

| Audit | User | Time (GMT) |
|------------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:25:12 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered 'Negative (NEGATIVE)' | (b) (4) (b) (4), (b) (6) | 21 Jan 2021 16:42:25 |

US3712094

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

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:25:14

[Was FSH sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:25:12 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 21 Jan 2021 16:42:25 |

US3712094

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

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:25:14

[Collection date](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:25:12 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Jan 2021 16:42:25 |

US3712094

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

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:25:14

[Collection time](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:25:12 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Jan 2021 16:42:25 |

US3712094

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

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| User entered empty. | System | 21 Jan 2021 16:42:25 |

US3712094

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

Form: Exposure

Generated On: 10 Jun 2021 09:25:14

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:25:20 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 21 Jan 2021 16:44:19 |

US3712094

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

Form: Exposure

Generated On: 10 Jun 2021 09:25:14

[If No, reason not given](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:25:20 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Jan 2021 16:44:19 |

US3712094

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

Form: Exposure

Generated On: 10 Jun 2021 09:25:14

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) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:25:20 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Jan 2021 16:44:19 |

US3712094

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

Form: Exposure

Generated On: 10 Jun 2021 09:25:14

[What was the study treatment? \(Unblinded\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| User entered 'mRNA-1273' | System | 21 Jan 2021 16:44:19 |
| DataPoint set to visible. | System | 21 Jan 2021 16:42:13 |

US3712094

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

Form: Exposure

Generated On: 10 Jun 2021 09:25:14

What was the treatment date? (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:25:20 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered '30 Dec 2020' | (b) (4) (b) (4), (b) (6) | 21 Jan 2021 16:44:19 |

US3712094

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

Form: Exposure

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:25:20 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered '15:15' | (b) (4) (b) (4), (b) (6) | 21 Jan 2021 16:44:19 |

US3712094

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

Form: Exposure

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| User entered '30 Dec 2020 15:15' | System | 21 Jan 2021 16:44:19 |

US3712094

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

Form: Exposure

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|------------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:25:20 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered 'Left Arm (LEFT ARM)' | (b) (4) (b) (4), (b) (6) | 21 Jan 2021 16:44:19 |

US3712094

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

Form: Exposure

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:25:20 |
| User entered 'ONCE' | System | 21 Jan 2021 16:44:19 |

US3712094

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

Form: Exposure

Generated On: 10 Jun 2021 09:25:14

[What was the route of administration for the study treatment?](#)

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| User entered 'INTRAMUSCULAR' | System | 21 Jan 2021 16:44:19 |

US3712094

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:25:14

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:25:33 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 21 Jan 2021 16:41:46 |

US3712094

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:25:33 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered '30 Dec 2020' | (b) (4) (b) (4), (b) (6) | 21 Jan 2021 16:41:46 |

US3712094

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:25:14

[Collection time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:25:33 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered '14:27' | (b) (4) (b) (4), (b) (6) | 21 Jan 2021 16:41:46 |

US3712094

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| User entered '30 Dec 2020 14:27' | System | 21 Jan 2021 16:41:46 |

US3712094

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:25:14

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:26:41 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 21 Jan 2021 16:41:52 |

US3712094

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:26:41 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered '30 Dec 2020' | (b) (4) (b) (4), (b) (6) | 21 Jan 2021 16:41:52 |

US3712094

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:25:14

[Collection time \(00:00 - 23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:26:41 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered '14:32' | (b) (4) (b) (4), (b) (6) | 21 Jan 2021 16:41:52 |

US3712094

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| User entered '30 Dec 2020 14:32' | System | 21 Jan 2021 16:41:52 |

US3712094

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

Form: Continuing

Generated On: 10 Jun 2021 09:25:14

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:26:44 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 21 Jan 2021 16:44:24 |

US3712094

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

Form: Continuing

Generated On: 10 Jun 2021 09:25:14

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| User entered 'I' | System | 21 Jan 2021 16:44:24 |

US3712094

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:25:14

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:27:15 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 21 Jan 2021 16:48:40 |

US3712094

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:25:14

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:27:15 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered '06 Jan 2021' | (b) (4) (b) (4), (b) (6) | 21 Jan 2021 16:48:40 |

US3712094

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:25:14

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:27:15 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) (b) (4), (b) (6) | 21 Jan 2021 16:48:40 |

US3712094

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:25:14

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:27:15 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Jan 2021 16:48:40 |

US3712094

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:25:14

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:28:16 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 21 Jan 2021 16:48:42 |

US3712094

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:25:14

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| User entered 'I' | System | 21 Jan 2021 16:48:42 |

US3712094

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:25:14

[OLD29 Placebo Flag](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| User entered '1' | System | 21 Jan 2021 16:48:42 |
| DataPoint set to visible. | System | 21 Jan 2021 16:48:42 |

US3712094

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:25:14

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:28:33 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 22 Feb 2021 13:01:06 |

US3712094

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:28:33 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered '01 Feb 2021' | (b) (4) (b) (4), (b) (6) | 22 Feb 2021 13:01:06 |

US3712094

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:28:33 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered 'Clinic (Clinic)' | (b) (4) (b) (4), (b) (6) | 22 Feb 2021 13:01:06 |

US3712094

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:25:14

[Folder OID](#)

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| User entered 'OLD29' | System | 22 Feb 2021 13:01:06 |

US3712094

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:14

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| User accepted default value 'Pre-Dose (PREDOSE)' | (b) (4), (b) (6) | 22 Feb 2021 13:02:14 |

US3712094

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:14

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:30:22 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 22 Feb 2021 13:02:14 |

US3712094

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:14

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:30:22 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered '01 Feb 2021' | (b) (4) (b) (4), (b) (6) | 22 Feb 2021 13:02:14 |

US3712094

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:14

[Time of assessment \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:30:22 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered '11:35' | (b) (4) (b) (4), (b) (6) | 22 Feb 2021 13:02:14 |

US3712094

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| User entered '01 Feb 2021 11:35' | System | 22 Feb 2021 13:02:14 |

US3712094

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:30:22 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered '37.1' C | (b) (4) (b) (4), (b) (6) | 22 Feb 2021 13:02:14 |

US3712094

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:14

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:30:22 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered 'Oral (Oral)' | (b) (4) (b) (4), (b) (6) | 22 Feb 2021 13:02:14 |

US3712094

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:14

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:30:22 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 22 Feb 2021 13:02:14 |

US3712094

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:14

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:30:22 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered '72' | (b) (4) (b) (4), (b) (6) | 22 Feb 2021 13:02:14 |

US3712094

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:14

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| User entered 'bpm' | System | 22 Feb 2021 13:02:14 |

US3712094

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:30:22 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered '17' | (b) (4) (b) (4), (b) (6) | 22 Feb 2021 13:02:14 |

US3712094

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:14

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| User entered 'breaths/min' | System | 22 Feb 2021 13:02:14 |

US3712094

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:30:22 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered '102' | (b) (4) (b) (4), (b) (6) | 22 Feb 2021 13:02:14 |

US3712094

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:14

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| User entered 'mmHg' | System | 22 Feb 2021 13:02:14 |

US3712094

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:30:22 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered '68' | (b) (4) (b) (4), (b) (6) | 22 Feb 2021 13:02:14 |

US3712094

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:14

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| User entered 'mmHg' | System | 22 Feb 2021 13:02:14 |

US3712094

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:14

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| User accepted default value 'Post-Dose (POSTDOSE)' | (b) (4), (b) (6) | 22 Feb 2021 13:02:14 |

US3712094

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:14

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:30:22 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 22 Feb 2021 13:02:14 |

US3712094

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:14

[Date of assessment \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:30:22 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered '01 Feb 2021' | (b) (4) (b) (4), (b) (6) | 22 Feb 2021 13:02:14 |

US3712094

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:14

[Time of assessment \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:30:22 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered '12:36' | (b) (4) (b) (4), (b) (6) | 22 Feb 2021 13:02:14 |

US3712094

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| User entered '01 Feb 2021 12:36' | System | 22 Feb 2021 13:02:14 |

US3712094

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:30:22 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered '36.9' C | (b) (4) (b) (4), (b) (6) | 22 Feb 2021 13:02:14 |

US3712094

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:14

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:30:22 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered 'Oral (Oral)' | (b) (4) (b) (4), (b) (6) | 22 Feb 2021 13:02:14 |

US3712094

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:14

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:30:22 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 22 Feb 2021 13:02:14 |

US3712094

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:14

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:30:22 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered '97' | (b) (4) (b) (4), (b) (6) | 22 Feb 2021 13:02:14 |

US3712094

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:14

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| User entered 'bpm' | System | 22 Feb 2021 13:02:14 |

US3712094

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:30:22 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered '16' | (b) (4) (b) (4), (b) (6) | 22 Feb 2021 13:02:14 |

US3712094

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:14

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| User entered 'breaths/min' | System | 22 Feb 2021 13:02:14 |

US3712094

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:30:22 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered '114' | (b) (4) (b) (4), (b) (6) | 22 Feb 2021 13:02:14 |

US3712094

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:14

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| User entered 'mmHg' | System | 22 Feb 2021 13:02:14 |

US3712094

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:30:22 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered '70' | (b) (4) (b) (4), (b) (6) | 22 Feb 2021 13:02:14 |

US3712094

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:14

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| User entered 'mmHg' | System | 22 Feb 2021 13:02:14 |

US3712094

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:25:14

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:30:26 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 22 Feb 2021 13:02:17 |

US3712094

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:25:14

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:30:26 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 22 Feb 2021 13:02:17 |

US3712094

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:25:14

[Was the pregnancy test performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:30:30 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 22 Feb 2021 13:01:21 |

US3712094

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:25:14

Date of test (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:30:30 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered '01 Feb 2021' | (b) (4) (b) (4), (b) (6) | 22 Feb 2021 13:01:21 |

US3712094

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:25:14

[Test performed](#)

| Audit | User | Time (GMT) |
|------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:30:30 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered 'Urine (URINE)' | (b) (4) (b) (4), (b) (6) | 22 Feb 2021 13:01:21 |

US3712094

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:25:14

[Result](#)

| Audit | User | Time (GMT) |
|------------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:30:30 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered 'Negative (NEGATIVE)' | (b) (4) (b) (4), (b) (6) | 22 Feb 2021 13:01:21 |

US3712094

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:25:14

[Was FSH sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:30:30 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 22 Feb 2021 13:01:21 |

US3712094

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:25:14

[Collection date](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:30:30 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 22 Feb 2021 13:01:21 |

US3712094

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:25:14

[Collection time](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:30:30 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 22 Feb 2021 13:01:21 |

US3712094

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| User entered empty. | System | 22 Feb 2021 13:01:21 |

US3712094

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:25:14

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:30:40 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 22 Feb 2021 13:02:41 |

US3712094

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:25:14

[If No, reason not given](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:30:40 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 22 Feb 2021 13:02:41 |

US3712094

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:25:14

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) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:30:40 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 22 Feb 2021 13:02:41 |

US3712094

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:25:14

[What was the study treatment? \(Unblinded\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| User entered 'mRNA-1273' | System | 22 Feb 2021 13:02:41 |
| DataPoint set to visible. | System | 21 Jan 2021 16:48:42 |

US3712094

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:25:14

[What was the treatment date? \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:30:40 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered '01 Feb 2021' | (b) (4) (b) (4), (b) (6) | 22 Feb 2021 13:02:41 |

US3712094

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:30:40 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered '12:06' | (b) (4) (b) (4), (b) (6) | 22 Feb 2021 13:02:41 |

US3712094

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| User entered '01 Feb 2021 12:06' | System | 22 Feb 2021 13:02:41 |

US3712094

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|------------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:30:40 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered 'Left Arm (LEFT ARM)' | (b) (4) (b) (4), (b) (6) | 22 Feb 2021 13:02:41 |

US3712094

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:30:40 |
| User entered 'ONCE' | System | 22 Feb 2021 13:02:41 |

US3712094

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:25:14

[What was the route of administration for the study treatment?](#)

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| User entered 'INTRAMUSCULAR' | System | 22 Feb 2021 13:02:41 |

US3712094

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:25:14

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:30:43 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 22 Feb 2021 13:02:57 |

US3712094

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:25:14

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| User entered 'I' | System | 22 Feb 2021 13:02:57 |

US3712094

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:25:14

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:32:44 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 22 Feb 2021 13:03:56 |

US3712094

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:25:14

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:32:44 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered '11 Feb 2021' | (b) (4) (b) (4), (b) (6) | 22 Feb 2021 13:03:56 |

US3712094

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:25:14

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:32:44 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) (b) (4), (b) (6) | 22 Feb 2021 13:03:56 |

US3712094

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:25:14

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:32:44 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 22 Feb 2021 13:03:56 |

US3712094

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:25:14

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:35:01 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 22 Feb 2021 13:04:00 |

US3712094

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:25:14

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| User entered 'I' | System | 22 Feb 2021 13:04:00 |

US3712094

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:25:14

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:35:20 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 19 Mar 2021 13:44:19 |

US3712094

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:35:20 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered '08 Mar 2021' | (b) (4) (b) (4), (b) (6) | 19 Mar 2021 13:44:19 |

US3712094

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:35:20 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered 'Clinic (Clinic)' | (b) (4) (b) (4), (b) (6) | 19 Mar 2021 13:44:19 |

US3712094

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:25:14

[Folder OID](#)

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| User entered 'OLD57' | System | 19 Mar 2021 13:44:19 |

US3712094

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:25:14

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:35:50 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 19 Mar 2021 13:44:43 |

US3712094

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:25:14

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:35:50 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 19 Mar 2021 13:44:43 |

US3712094

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:25:14

[Time of assessment \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:35:50 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 19 Mar 2021 13:44:43 |

US3712094

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| User entered empty. | System | 19 Mar 2021 13:44:43 |

US3712094

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:35:50 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 19 Mar 2021 13:44:43 |

US3712094

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:25:14

[Route of measurement](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:35:50 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 19 Mar 2021 13:44:43 |

US3712094

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:25:14

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:35:50 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 19 Mar 2021 13:44:43 |

US3712094

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:25:14

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:35:50 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 19 Mar 2021 13:44:43 |

US3712094

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:25:14

[Pulse units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| User entered empty. | System | 19 Mar 2021 13:44:43 |

US3712094

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:35:50 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 19 Mar 2021 13:44:43 |

US3712094

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:25:14

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| User entered empty. | System | 19 Mar 2021 13:44:43 |

US3712094

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:35:50 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 19 Mar 2021 13:44:43 |

US3712094

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:25:14

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| User entered empty. | System | 19 Mar 2021 13:44:43 |

US3712094

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:35:50 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 19 Mar 2021 13:44:43 |

US3712094

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:25:14

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| User entered empty. | System | 19 Mar 2021 13:44:43 |

US3712094

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:25:14

[Height \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| | | |

US3712094

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:25:14

[Weight \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |

US3712094

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:25:14

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:35:55 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 19 Mar 2021 13:44:46 |

US3712094

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:25:14

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:35:55 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 19 Mar 2021 13:44:46 |

US3712094

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:25:14

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:36:05 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 19 Mar 2021 13:44:52 |

US3712094

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:25:14

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:36:05 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered '08 Mar 2021' | (b) (4) (b) (4), (b) (6) | 19 Mar 2021 13:44:52 |

US3712094

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:25:14

[Collection time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:36:05 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered '10:45' | (b) (4) (b) (4), (b) (6) | 19 Mar 2021 13:44:52 |

US3712094

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 18:42:34 |
| User entered '08 Mar 2021 10:45' | System | 19 Mar 2021 13:44:52 |

US3712094

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:25:14

[Did the participant experience any adverse events?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 10:21:14 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 20:03:30 |
| User signature succeeded. | William Smith (b) (4) | 12 Mar 2021 22:21:26 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 21 Jan 2021 16:36:46 |

US3712094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:25:14

[AEID](#)

| Audit | User | Time (GMT) |
|---------------------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 18 Apr 2021 23:29:00 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 19:32:10 |
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Feb 2021 14:42:08 |
| User entered | System | 24 Feb 2021 14:41:48 |
| 'USA-US068-2021-mRNA-1273-P301000015' | | |
| User entered 'New' | (b) (4), (b) (6) | 24 Feb 2021 14:41:48 |

US3712094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:25:14

[Adverse event](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 18 Apr 2021 23:29:00 |
| User closed query 'Adverse Event term should only include the actual event, the procedure is captured on the con procedure form.' (Site from CRA). | (b) (4) (b) (4), (b) (6) | 14 Apr 2021 20:07:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:07:47 |
| User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Abdominal and gastrointestinal infections, PT: Appendicitis, LLT: Appendicitis - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 19 Mar 2021 13:31:53 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 19 Mar 2021 13:31:53 |
| Data point term sent to Coder | System | 19 Mar 2021 13:30:44 |
| Query 'Adverse Event term should only include the actual event, the procedure is captured on the con procedure form.' answered with 'updated' (Site from CRA). | (b) (4), (b) (6) | 19 Mar 2021 13:30:28 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 19 Mar 2021 13:30:22 |
| Coding entries removed. | (b) (4), (b) (6) | 19 Mar 2021 13:30:22 |
| User entered 'APPENDICITIS' reason for change: Data Entry Error | (b) (4), (b) (6) | 19 Mar 2021 13:30:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 19:32:12 |
| User opened query 'Adverse Event term should only include the actual event, the procedure is captured on the con procedure form.' (Site from CRA). | (b) (4), (b) (6) | 25 Feb 2021 18:13:48 |
| User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Abdominal and gastrointestinal infections, PT: Appendicitis, LLT: Appendicitis - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 21 Jan 2021 16:45:04 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 21 Jan 2021 16:45:04 |
| Data point term sent to Coder | System | 21 Jan 2021 16:38:29 |
| User entered 'appendicitis with appendectomy' | (b) (4), (b) (6) | 21 Jan 2021 16:37:43 |

US3712094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:25:14

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 18 Apr 2021 23:29:00 |
| User closed query 'Please confirm, as subject went to the Emergency Room for this condition. ' (Site from CRA). | (b) (4) (b) (4), (b) (6) | 14 Apr 2021 20:08:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:08:06 |
| Query 'Please confirm, as subject went to the Emergency Room for this condition. ' answered with 'updated' (Site from CRA). | (b) (4), (b) (6) | 19 Mar 2021 13:32:23 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 19 Mar 2021 13:32:17 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | (b) (4), (b) (6) | 19 Mar 2021 13:32:17 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 19:32:13 |
| User opened query 'Please confirm, as subject went to the Emergency Room for this condition. ' (Site from CRA). | (b) (4), (b) (6) | 25 Feb 2021 18:15:13 |
| User entered 'No (N)' | (b) (4), (b) (6) | 21 Jan 2021 16:37:43 |

US3712094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:25:14

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 18 Apr 2021 23:29:00 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 19:32:15 |
| User entered 'No (N)' | (b) (4), (b) (6) | 21 Jan 2021 16:37:43 |

US3712094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:25:14

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 18 Apr 2021 23:29:00 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 19:32:17 |
| User entered 'No (N)' | (b) (4), (b) (6) | 21 Jan 2021 16:37:43 |

US3712094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:25:14

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 18 Apr 2021 23:29:00 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 14 Apr 2021 20:08:15 |
| User closed query 'Please confirm, as subject seems to have reported symptoms on 20Dec2020, and was diagnosed on 21Dec2020. If confirmed, consider updating start date to 20Dec2020.' (Site from CRA). | (b) (4), (b) (6) | 14 Apr 2021 20:08:12 |
| User closed query 'PV Query: As start date of event was updated to 20 Dec, please correct date in case narrative section to match date event onset.' (Site from Safety). | (b) (4), (b) (6) | 30 Mar 2021 17:13:39 |
| Query 'PV Query: As start date of event was updated to 20 Dec, please correct date in case narrative section to match date event onset.' answered with 'updated' (Site from Safety). | (b) (4), (b) (6) | 30 Mar 2021 13:51:30 |
| User opened query 'PV Query: As start date of event was updated to 20 Dec, please correct date in case narrative section to match date event onset.' (Site from Safety). | (b) (4), (b) (6) | 29 Mar 2021 05:00:04 |
| Query 'Please confirm, as subject seems to have reported symptoms on 20Dec2020, and was diagnosed on 21Dec2020. If confirmed, consider updating start date to 20Dec2020.' answered with 'updated' (Site from CRA). | (b) (4), (b) (6) | 19 Mar 2021 13:32:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 19 Mar 2021 13:32:17 |
| User entered '20 Dec 2020' reason for change: Data Entry Error | (b) (4), (b) (6) | 19 Mar 2021 13:32:17 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 19:32:42 |
| User opened query 'Please confirm, as subject seems to have reported symptoms on 20Dec2020, and was diagnosed on 21Dec2020. If confirmed, consider updating start date to 20Dec2020.' (Site from CRA). | (b) (4), (b) (6) | 25 Feb 2021 18:24:49 |
| User entered '21 Dec 2020' | (b) (4), (b) (6) | 21 Jan 2021 16:37:43 |

US3712094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:25:14

[Start time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 18 Apr 2021 23:29:00 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 19:32:45 |
| User entered empty. | (b) (4), (b) (6) | 21 Jan 2021 16:37:43 |

US3712094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:25:14

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 21 Jan 2021 16:37:43 |

US3712094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:25:14

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 18 Apr 2021 23:29:00 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 19:32:47 |
| User entered 'No (N)' | (b) (4), (b) (6) | 21 Jan 2021 16:37:43 |

US3712094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:25:14

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 18 Apr 2021 23:29:00 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 19:32:49 |
| User entered '22 Dec 2020' reason for change: Data Entry Error | (b) (4), (b) (6) | 23 Feb 2021 15:54:22 |
| User entered '21 Dec 2020' | (b) (4), (b) (6) | 21 Jan 2021 16:37:43 |

US3712094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:25:14

[End time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 18 Apr 2021 23:29:00 |
| DataPoint Verified. | (b) (4) | 25 Feb 2021 19:32:51 |
| User entered empty. | (b) (4), (b) (6) | 21 Jan 2021 16:37:43 |

US3712094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:25:14

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 21 Jan 2021 16:37:43 |

US3712094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:25:14

[Severity](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 18 Apr 2021 23:29:00 |
| User closed query 'Per paper form of the SAE report, "moderate" is noted. if confirmed, please update.' (Site from CRA). | (b) (4) (b) (4), (b) (6) | 14 Apr 2021 20:09:37 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:09:32 |
| Query 'Per paper form of the SAE report, "moderate" is noted. if confirmed, please update.' answered with 'updated' (Site from CRA). | (b) (4), (b) (6) | 19 Mar 2021 13:32:38 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 19 Mar 2021 13:32:17 |
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error | (b) (4), (b) (6) | 19 Mar 2021 13:32:17 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 19:32:53 |
| User opened query 'Per paper form of the SAE report, "moderate" is noted. if confirmed, please update.' (Site from CRA). | (b) (4), (b) (6) | 25 Feb 2021 18:15:37 |
| User entered 'Grade 1/Mild (Grade 1/Mild)' | (b) (4), (b) (6) | 21 Jan 2021 16:37:43 |

US3712094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:25:14

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 18 Apr 2021 23:29:00 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 19:32:55 |
| 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 | 23 Feb 2021 16:11:29 |
| 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 | 23 Feb 2021 16:06:18 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | (b) (4), (b) (6) | 23 Feb 2021 16:06:18 |
| User entered 'No (N)' | (b) (4), (b) (6) | 21 Jan 2021 16:37:43 |

US3712094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:25:14

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 18 Apr 2021 23:29:00 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 19:32:57 |
| User entered '0' | (b) (4), (b) (6) | 21 Jan 2021 16:37:43 |

US3712094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:25:14

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 18 Apr 2021 23:29:00 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 19:32:58 |
| User entered '0' | (b) (4), (b) (6) | 21 Jan 2021 16:37:43 |

US3712094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:25:14

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 18 Apr 2021 23:29:00 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 19:32:59 |
| User entered '1' reason for change: Data Entry Error | (b) (4), (b) (6) | 23 Feb 2021 16:11:29 |
| User entered '0' | (b) (4), (b) (6) | 21 Jan 2021 16:37:43 |

US3712094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:25:14

[Hospital Admission Date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 18 Apr 2021 23:29:00 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 19:33:02 |
| User entered '21 Dec 2020' reason for change: Data Entry Error | (b) (4), (b) (6) | 23 Feb 2021 16:11:29 |
| User entered empty. | (b) (4), (b) (6) | 21 Jan 2021 16:37:43 |

US3712094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:25:14

Hospital Discharge Date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 18 Apr 2021 23:29:00 |
| User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety). | (b) (4) (b) (4), (b) (6) | 14 Apr 2021 18:18:40 |
| Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' answered with 'We did not receive medical discharged summary ' (Site from Safety). | (b) (4), (b) (6) | 13 Apr 2021 12:26:03 |
| User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety). | (b) (4), (b) (6) | 04 Mar 2021 20:08:48 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 19:33:03 |
| User entered '22 Dec 2020' reason for change: Data Entry Error | (b) (4), (b) (6) | 23 Feb 2021 16:11:29 |
| User entered empty. | (b) (4), (b) (6) | 21 Jan 2021 16:37:43 |

US3712094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:25:14

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 18 Apr 2021 23:29:00 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 19:33:05 |
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4), (b) (6) | 23 Feb 2021 16:11:29 |
| User entered empty. | (b) (4), (b) (6) | 21 Jan 2021 16:37:43 |

US3712094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:25:14

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 18 Apr 2021 23:29:00 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 19:33:06 |
| User entered empty. | (b) (4), (b) (6) | 21 Jan 2021 16:37:43 |

US3712094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:25:14

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 18 Apr 2021 23:29:00 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 19:33:08 |
| User entered '0' | (b) (4), (b) (6) | 21 Jan 2021 16:37:43 |

US3712094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:25:14

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 18 Apr 2021 23:29:00 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 19:33:09 |
| User entered '0' | (b) (4), (b) (6) | 21 Jan 2021 16:37:43 |

US3712094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:25:14

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 18 Apr 2021 23:29:00 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 19:33:11 |
| User entered '0' | (b) (4), (b) (6) | 21 Jan 2021 16:37:43 |

US3712094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:25:14

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 18 Apr 2021 23:29:00 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 19:33:13 |
| User entered 'Not Related (NOT RELATED)' | (b) (4), (b) (6) | 21 Jan 2021 16:37:43 |

US3712094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:25:14

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 18 Apr 2021 23:29:00 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 19:33:14 |
| User entered 'Not Related (NOT RELATED)' | (b) (4), (b) (6) | 21 Jan 2021 16:37:43 |

US3712094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:25:14

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 18 Apr 2021 23:29:00 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 19:33:16 |
| User entered 'Not Applicable (NOT APPLICABLE)' | (b) (4), (b) (6) | 21 Jan 2021 16:37:43 |

US3712094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:25:14

[None](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 18 Apr 2021 23:29:00 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 19:33:18 |
| User entered '0' | (b) (4), (b) (6) | 21 Jan 2021 16:37:43 |

US3712094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:25:14

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 18 Apr 2021 23:29:00 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 14 Apr 2021 20:09:51 |
| User closed query 'Con meds were administered while in hospital and subject was discharged with Zofran. Please review and update as needed.' (Site from CRA). | (b) (4), (b) (6) | 14 Apr 2021 20:09:50 |
| Query 'Con meds were administered while in hospital and subject was discharged with Zofran. Please review and update as needed.' answered with 'updated' (Site from CRA). | (b) (4), (b) (6) | 23 Mar 2021 14:36:16 |
| User entered '1' reason for change: Data Entry Error | (b) (4), (b) (6) | 19 Mar 2021 13:32:17 |
| User opened query 'Con meds were administered while in hospital and subject was discharged with Zofran. Please review and update as needed.' (Site from CRA). | (b) (4), (b) (6) | 25 Feb 2021 19:33:46 |
| User entered '0' | (b) (4), (b) (6) | 21 Jan 2021 16:37:43 |

US3712094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:25:14

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 18 Apr 2021 23:29:00 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 19:33:48 |
| User entered 'I' | (b) (4), (b) (6) | 21 Jan 2021 16:37:43 |

US3712094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:25:14

[Outcome](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 18 Apr 2021 23:29:00 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 19:33:49 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | (b) (4), (b) (6) | 21 Jan 2021 16:37:43 |

US3712094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:25:14

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 18 Apr 2021 23:29:00 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 19:33:50 |
| User entered empty. | (b) (4), (b) (6) | 21 Jan 2021 16:37:43 |

US3712094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:25:14

[Narrative](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 18 Apr 2021 23:29:00 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 14 Apr 2021 20:10:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 30 Mar 2021 13:50:37 |
| User entered 'SUBJECT ARRIVED AT PARKWEST MEDICAL CENTER ON 21 DEC 2020 WITH RIGHT LOWER QUADRANT ABDOMINAL PAIN THAT STARTED ON 20 DEC 2020 EARLY AM WITH VOMITING. CT SCAN WAS OBTAINED IN ED AND SHOWED ACUTE APPENDICITIS WITH APPENDIX FLUID FILLED WITH NUMEROUS APPENDICOLITHS AT THE TIP, MEASURING UP TO 7MM, WITHOUT PERFORATION AND SUBJECT WAS PREPARED FOR EMERGENT SURGERY WHICH SHE HAD ON 21 DEC 2020. LAB WORK RESULTED AS FOLLOWED: NEUTROPHIL: 91.3, LYMPHOCYTE: 4.0, WBC: 16.9, LIPASE: 25, HCG URINE: NEGATIVE, UA WBC: 11, SARS-COV-2 ANTIGEN: NEGATIVE. PATHOLOGY REPORT: FORMALIN "APPENDIX" IS A 12CM IN LENGTH X 0.7CM IN AVERAGE DIAMETER VERIFORM APPENDIX WITH ASSOCIATED FAT. THE SEROSA IS PURPLE TO PINK AND FOCALLY ROUGHENED. THE SOFT YELLOW MUCOSAL SURFACES ARE FOCALLY HEMORRHAGIC. THE NONPERFORATING WALL AVERAGE 0.2CM IN THICKNESS. THERE ARE NO CONTENTS OR FECALITH IN THE LUMEN. THE MARGIN IS INKED BLUE. A1 REPRESENTATIVE SECTIONS. PERFORMED 21 DEC 2020.' reason for change: Data Entry Error | (b) (4), (b) (6) | 30 Mar 2021 13:50:37 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 19:33:53 |
| User closed query 'Please remove patient's name from narrative.' (Site from CRA). | (b) (4), (b) (6) | 25 Feb 2021 18:10:15 |
| Query 'Please remove patient's name from narrative.' answered with 'corrected' (Site from CRA). | (b) (4), (b) (6) | 25 Feb 2021 17:06:59 |

US3712094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:25:14

[Narrative](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| User entered 'SUBJECT ARRIVED AT PARKWEST MEDICAL CENTER ON 21 DEC 2020 WITH RIGHT LOWER QUADRANT ABDOMINAL PAIN THAT STARTED ON 21 DEC 2020 EARLY AM WITH VOMITING. CT SCAN WAS OBTAINED IN ED AND SHOWED ACUTE APPENDICITIS WITH APPENDIX FLUID FILLED WITH NUMEROUS APPENDICOLITHS AT THE TIP, MEASURING UP TO 7MM, WITHOUT PERFORATION AND SUBJECT WAS PREPARED FOR EMERGENT SURGERY WHICH SHE HAD ON 21 DEC 2020. LAB WORK RESULTED AS FOLLOWED: NEUTROPHIL: 91.3, LYMPHOCYTE: 4.0, WBC: 16.9, LIPASE: 25, HCG URINE: NEGATIVE, UA WBC: 11, SARS-COV-2 ANTIGEN: NEGATIVE. PATHOLOGY REPORT: FORMALIN "APPENDIX" IS A 12CM IN LENGTH X 0.7CM IN AVERAGE DIAMETER VERIFORM APPENDIX WITH ASSOCIATED FAT. THE SEROSA IS PURPLE TO PINK AND FOCALLY ROUGHENED. THE SOFT YELLOW MUCOSAL SURFACES ARE FOCALLY HEMORRHAGIC. THE NONPERFORATING WALL AVERAGE 0.2CM IN THICKNESS. THERE ARE NO CONTENTS OR FECALITH IN THE LUMEN. THE MARGIN IS INKED BLUE. A1 REPRESENTATIVE SECTIONS. PERFORMED 21 DEC 2020.' | (b) (4), (b) (6) | 25 Feb 2021 17:06:53 |
| reason for change: Data Entry Error User opened query 'Please remove patient's name from narrative.' (Site from CRA). | (b) (4), (b) (6) | 25 Feb 2021 16:54:04 |

US3712094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:25:14

[Narrative](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| User entered 'Subject arrived at Parkwest Medical center on 21 DEC 2020 with right lower quadrant abdominal pain that started on 21 DEC 2020 early AM with vomiting. CT scan was obtained in ED and showed acute appendicitis with appendix fluid filled with numerous appendicoliths at the tip, measuring up to 7mm, without perforation and subject was prepared for emergent surgery which she had on 21 DEC 2020. Lab work resulted as followed: Neutrophil: 91.3, lymphocyte: 4.0, wbc: 16.9, lipase: 25, hCG urine: Negative, UA WBC: 11, SARS-CoV-2 antigen: negative. Pathology report: received in formalin labeled "(b) (6) (b) (6)" and "appendix" is a 12cm in length x 0.7cm in average diameter veriform appendix with associated fat. The serosa is purple to pink and focally roughened. The soft yellow mucosal surfaces are focally hemorrhagic. The nonperforating wall average 0.2cm in thickness. There are no contents or fecalith in the lumen. The margin is inked blue. A1 representative sections. Performed 21 DEC 2020.' | (b) (4), (b) (6) | 23 Feb 2021 16:06:18 |
| reason for change: Data Entry Error User entered empty. | (b) (4), (b) (6) | 21 Jan 2021 16:37:43 |

US3712094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:25:14

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 23 Feb 2021 16:06:18 |
| User entered '0' | System | 21 Jan 2021 16:37:43 |

US3712094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:25:14

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 19 Mar 2021 13:32:17 |
| User entered '0' | System | 21 Jan 2021 16:37:43 |

US3712094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:25:14

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '0' | System | 23 Feb 2021 16:11:29 |

US3712094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:25:14

[Adverse event](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 18 Apr 2021 23:29:00 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 14 Apr 2021 20:15:56 |
| User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Reproductive neoplasms female benign, HLT: Uterine neoplasms benign, PT: Uterine leiomyoma, LLT: Uterine fibroids - version MedDRA\\23.0. | Coder Import (b) (4) | 30 Mar 2021 14:11:19 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 30 Mar 2021 14:11:19 |
| | (b) (4) | |
| Data point term sent to Coder | System | 30 Mar 2021 14:00:03 |
| User entered 'uterine fibroids' | (b) (4), (b) (6) | 30 Mar 2021 13:59:42 |
| | | |

US3712094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:25:14

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 18 Apr 2021 23:29:00 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 14 Apr 2021 20:15:56 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 30 Mar 2021 13:59:42 |

US3712094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:25:14

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 18 Apr 2021 23:29:00 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 14 Apr 2021 20:15:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 30 Mar 2021 13:59:42 |

US3712094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:25:14

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 18 Apr 2021 23:29:00 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 14 Apr 2021 20:15:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 30 Mar 2021 13:59:42 |

US3712094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 18 Apr 2021 23:29:00 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 14 Apr 2021 20:15:56 |
| User entered '21 Dec 2020' | (b) (4), (b) (6) | 30 Mar 2021 13:59:42 |

US3712094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:25:14

[Start time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 18 Apr 2021 23:29:00 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 14 Apr 2021 20:15:56 |
| User entered empty. | (b) (4), (b) (6) | 30 Mar 2021 13:59:42 |

US3712094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:25:14

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 30 Mar 2021 13:59:42 |

US3712094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:25:14

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 18 Apr 2021 23:29:00 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 14 Apr 2021 20:15:56 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 30 Mar 2021 13:59:42 |

US3712094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:25:14

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 18 Apr 2021 23:29:00 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 14 Apr 2021 20:15:56 |
| User entered empty. | (b) (4), (b) (6) | 30 Mar 2021 13:59:42 |

US3712094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:25:14

[End time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 18 Apr 2021 23:29:00 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 14 Apr 2021 20:15:56 |
| User entered empty. | (b) (4), (b) (6) | 30 Mar 2021 13:59:42 |

US3712094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:25:14

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 30 Mar 2021 13:59:42 |

US3712094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:25:14

[Severity](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 18 Apr 2021 23:29:00 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 14 Apr 2021 20:15:56 |
| User entered 'Grade 1/Mild (Grade 1/Mild)' | (b) (4), (b) (6) | 30 Mar 2021 13:59:42 |

US3712094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:25:14

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 18 Apr 2021 23:29:00 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 14 Apr 2021 20:15:56 |
| User entered 'No (N)' | (b) (4), (b) (6) | 30 Mar 2021 13:59:42 |

US3712094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:25:14

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 18 Apr 2021 23:29:00 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 14 Apr 2021 20:15:56 |
| User entered '0' | (b) (4), (b) (6) | 30 Mar 2021 13:59:42 |

US3712094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:25:14

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 18 Apr 2021 23:29:00 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 14 Apr 2021 20:15:56 |
| User entered '0' | (b) (4), (b) (6) | 30 Mar 2021 13:59:42 |

US3712094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:25:14

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 18 Apr 2021 23:29:00 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 14 Apr 2021 20:15:56 |
| User entered '0' | (b) (4), (b) (6) | 30 Mar 2021 13:59:42 |

US3712094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:25:14

[Hospital Admission Date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 18 Apr 2021 23:29:00 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 14 Apr 2021 20:15:56 |
| User entered empty. | (b) (4), (b) (6) | 30 Mar 2021 13:59:42 |

US3712094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:25:14

Hospital Discharge Date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 18 Apr 2021 23:29:00 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 14 Apr 2021 20:15:56 |
| User entered empty. | (b) (4), (b) (6) | 30 Mar 2021 13:59:42 |

US3712094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:25:14

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 18 Apr 2021 23:29:00 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 14 Apr 2021 20:15:56 |
| User entered empty. | (b) (4), (b) (6) | 30 Mar 2021 13:59:42 |

US3712094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:25:14

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 18 Apr 2021 23:29:00 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 14 Apr 2021 20:15:56 |
| User entered empty. | (b) (4), (b) (6) | 30 Mar 2021 13:59:42 |

US3712094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:25:14

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 18 Apr 2021 23:29:00 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 14 Apr 2021 20:15:56 |
| User entered '0' | (b) (4), (b) (6) | 30 Mar 2021 13:59:42 |

US3712094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:25:14

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 18 Apr 2021 23:29:00 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 14 Apr 2021 20:15:56 |
| User entered '0' | (b) (4), (b) (6) | 30 Mar 2021 13:59:42 |

US3712094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:25:14

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 18 Apr 2021 23:29:00 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 14 Apr 2021 20:15:56 |
| User entered '0' | (b) (4), (b) (6) | 30 Mar 2021 13:59:42 |

US3712094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:25:14

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 18 Apr 2021 23:29:00 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 14 Apr 2021 20:15:56 |
| User entered 'Not Related (NOT RELATED)' | (b) (4), (b) (6) | 30 Mar 2021 13:59:42 |

US3712094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:25:14

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 18 Apr 2021 23:29:00 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 14 Apr 2021 20:15:56 |
| User entered 'Not Related (NOT RELATED)' | (b) (4), (b) (6) | 30 Mar 2021 13:59:42 |

US3712094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:25:14

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 18 Apr 2021 23:29:00 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 14 Apr 2021 20:15:56 |
| User entered 'Not Applicable (NOT APPLICABLE)' | (b) (4), (b) (6) | 30 Mar 2021 13:59:42 |

US3712094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:25:14

[None](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 18 Apr 2021 23:29:00 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 14 Apr 2021 20:15:56 |
| User entered 'I' | (b) (4), (b) (6) | 30 Mar 2021 13:59:42 |

US3712094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:25:14

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 18 Apr 2021 23:29:00 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 14 Apr 2021 20:15:56 |
| User entered '0' | (b) (4), (b) (6) | 30 Mar 2021 13:59:42 |

US3712094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:25:14

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 18 Apr 2021 23:29:00 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 14 Apr 2021 20:15:56 |
| User entered '0' | (b) (4), (b) (6) | 30 Mar 2021 13:59:42 |

US3712094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:25:14

[Outcome](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 18 Apr 2021 23:29:00 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 14 Apr 2021 20:15:56 |
| User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' | (b) (4), (b) (6) | 30 Mar 2021 13:59:42 |

US3712094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:25:14

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 18 Apr 2021 23:29:00 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 14 Apr 2021 20:15:56 |
| User entered empty. | (b) (4), (b) (6) | 30 Mar 2021 13:59:42 |

US3712094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:25:14

[Narrative](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 18 Apr 2021 23:29:00 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 14 Apr 2021 20:15:56 |
| User entered empty. | (b) (4), (b) (6) | 30 Mar 2021 13:59:42 |

US3712094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:25:14

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '0' | System | 30 Mar 2021 13:59:42 |

US3712094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:25:14

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 30 Mar 2021 13:59:42 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:25:14

[Were any prior/concomitant medications and/or vaccinations taken?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 10:21:14 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:18:13 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 22 Sep 2020 16:17:14 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:25:14

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:19:48 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: VENLAFAXINE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 24 Sep 2020 10:24:49 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 24 Sep 2020 10:24:49 |
| Data point term sent to Coder | System | 22 Sep 2020 16:18:24 |
| User entered 'Venlafaxine' | (b) (4), (b) (6) | 22 Sep 2020 16:18:20 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:25:14

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:19:48 |
| User entered 'No (N)' | (b) (4), (b) (6) | 22 Sep 2020 16:18:20 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:25:14

[Indication](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:19:48 |
| User entered 'Bipolar Disorder Type II' | (b) (4), (b) (6) | 22 Sep 2020 16:18:20 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:25:14

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:19:48 |
| User entered '150' | (b) (4), (b) (6) | 22 Sep 2020 16:18:20 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:25:14

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:19:48 |
| User entered 'mg (mg)' | (b) (4), (b) (6) | 22 Sep 2020 16:18:20 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:25:14

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:19:48 |
| User entered empty. | (b) (4), (b) (6) | 22 Sep 2020 16:18:20 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:25:14

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:19:48 |
| User entered 'once daily (QD)' | (b) (4), (b) (6) | 22 Sep 2020 16:18:20 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:25:14

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:19:48 |
| User entered empty. | (b) (4), (b) (6) | 22 Sep 2020 16:18:20 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:25:14

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:19:48 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6) | 22 Sep 2020 16:18:20 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:25:14

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:19:48 |
| User entered empty. | (b) (4), (b) (6) | 22 Sep 2020 16:18:20 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:19:48 |
| User entered 'UN UNK 2016' | (b) (4), (b) (6) | 22 Sep 2020 16:18:20 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:25:14

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:19:48 |
| User entered '0' | (b) (4), (b) (6) | 22 Sep 2020 16:18:20 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:25:14

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:19:48 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 22 Sep 2020 16:18:20 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:25:14

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:19:48 |
| User entered empty. | (b) (4), (b) (6) | 22 Sep 2020 16:18:20 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:25:14

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:19:48 |
| User entered 'No (N)' | (b) (4), (b) (6) | 22 Sep 2020 16:18:20 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:25:14

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 22 Sep 2020 16:18:20 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:25:14

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 22 Sep 2020 16:18:20 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:25:14

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 22 Sep 2020 16:18:20 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:25:14

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 07 Oct 2020 18:19:48 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: DIAZEPINES, OXAZEPINES, THIAZEPINES AND OXEPINES, PRODUCT: QUETIAPINE FUMARATE, PRODUCTSYNONYM: SEROQUEL - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 22 Sep 2020 16:20:47 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 22 Sep 2020 16:20:47 |
| | (b) (4) | |
| Data point term sent to Coder | System | 22 Sep 2020 16:19:27 |
| User entered 'Seroquel' | (b) (4), (b) (6) | 22 Sep 2020 16:18:54 |
| | | |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:25:14

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:19:48 |
| User entered 'No (N)' | (b) (4), (b) (6) | 22 Sep 2020 16:18:54 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:25:14

[Indication](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:19:48 |
| User entered 'Bipolar Disorder Type II' | (b) (4), (b) (6) | 22 Sep 2020 16:18:54 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:25:14

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:19:48 |
| User entered '350' | (b) (4), (b) (6) | 22 Sep 2020 16:18:54 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:25:14

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:19:48 |
| User entered 'mg (mg)' | (b) (4), (b) (6) | 22 Sep 2020 16:18:54 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:25:14

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:19:48 |
| User entered empty. | (b) (4), (b) (6) | 22 Sep 2020 16:18:54 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:25:14

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:19:48 |
| User entered 'once daily (QD)' | (b) (4), (b) (6) | 22 Sep 2020 16:18:54 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:25:14

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:19:48 |
| User entered empty. | (b) (4), (b) (6) | 22 Sep 2020 16:18:54 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:25:14

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:19:48 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6) | 22 Sep 2020 16:18:54 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:25:14

[If route of administration is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:19:48 |
| User entered empty. | (b) (4), (b) (6) | 22 Sep 2020 16:18:54 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:19:48 |
| User entered 'UN Sep 2017' | (b) (4), (b) (6) | 22 Sep 2020 16:18:54 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:25:14

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:19:48 |
| User entered '0' | (b) (4), (b) (6) | 22 Sep 2020 16:18:54 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:25:14

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:19:48 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 22 Sep 2020 16:18:54 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:25:14

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:19:48 |
| User entered empty. | (b) (4), (b) (6) | 22 Sep 2020 16:18:54 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:25:14

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:19:48 |
| User entered 'No (N)' | (b) (4), (b) (6) | 22 Sep 2020 16:18:54 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:25:14

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 22 Sep 2020 16:18:54 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:25:14

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 22 Sep 2020 16:18:54 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:25:14

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 22 Sep 2020 16:18:54 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:25:14

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:19:48 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: OXCARBAZEPINE, PRODUCTSYNONYM: TRILEPTAL - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 27 Sep 2020 10:31:42 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 27 Sep 2020 10:31:42 |
| Data point term sent to Coder | System | 22 Sep 2020 16:20:28 |
| User entered 'Trileptal' | (b) (4), (b) (6) | 22 Sep 2020 16:19:31 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:25:14

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:19:48 |
| User entered 'No (N)' | (b) (4), (b) (6) | 22 Sep 2020 16:19:31 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:25:14

[Indication](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:19:48 |
| User entered 'Bipolar Disorder Type II' | (b) (4), (b) (6) | 22 Sep 2020 16:19:31 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:25:14

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:19:48 |
| User entered '300' | (b) (4), (b) (6) | 22 Sep 2020 16:19:31 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:25:14

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:19:48 |
| User entered 'mg (mg)' | (b) (4), (b) (6) | 22 Sep 2020 16:19:31 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:25:14

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:19:48 |
| User entered empty. | (b) (4), (b) (6) | 22 Sep 2020 16:19:31 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:25:14

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:19:48 |
| User entered 'once daily (QD)' | (b) (4), (b) (6) | 22 Sep 2020 16:19:31 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:25:14

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:19:48 |
| User entered empty. | (b) (4), (b) (6) | 22 Sep 2020 16:19:31 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:25:14

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:19:48 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6) | 22 Sep 2020 16:19:31 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:25:14

[If route of administration is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:19:48 |
| User entered empty. | (b) (4), (b) (6) | 22 Sep 2020 16:19:31 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:19:48 |
| User entered 'UN UNK 2015' | (b) (4), (b) (6) | 22 Sep 2020 16:19:31 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:25:14

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:19:48 |
| User entered '0' | (b) (4), (b) (6) | 22 Sep 2020 16:19:31 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:25:14

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:19:48 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 22 Sep 2020 16:19:31 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:25:14

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:19:48 |
| User entered empty. | (b) (4), (b) (6) | 22 Sep 2020 16:19:31 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:25:14

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:19:48 |
| User entered 'No (N)' | (b) (4), (b) (6) | 22 Sep 2020 16:19:31 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:25:14

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 22 Sep 2020 16:19:31 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:25:14

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 22 Sep 2020 16:19:31 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:25:14

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 22 Sep 2020 16:19:31 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:25:14

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:19:48 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 22 Sep 2020 23:29:47 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 22 Sep 2020 23:29:47 |
| Data point term sent to Coder | System | 22 Sep 2020 16:20:31 |
| User entered 'Gabapentin' | (b) (4), (b) (6) | 22 Sep 2020 16:20:01 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:25:14

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:19:48 |
| User entered 'No (N)' | (b) (4), (b) (6) | 22 Sep 2020 16:20:01 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:25:14

[Indication](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:19:48 |
| User entered 'Bipolar Disorder Type II' | (b) (4), (b) (6) | 22 Sep 2020 16:20:01 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:25:14

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:19:48 |
| User entered '600' | (b) (4), (b) (6) | 22 Sep 2020 16:20:01 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:25:14

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:19:48 |
| User entered 'mg (mg)' | (b) (4), (b) (6) | 22 Sep 2020 16:20:01 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:25:14

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:19:48 |
| User entered empty. | (b) (4), (b) (6) | 22 Sep 2020 16:20:01 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:25:14

[Frequency](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:19:48 |
| User entered 'twice daily (BID)' | (b) (4), (b) (6) | 22 Sep 2020 16:20:01 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:25:14

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:19:48 |
| User entered empty. | (b) (4), (b) (6) | 22 Sep 2020 16:20:01 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:25:14

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:19:48 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6) | 22 Sep 2020 16:20:01 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:25:14

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:19:48 |
| User entered empty. | (b) (4), (b) (6) | 22 Sep 2020 16:20:01 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:19:48 |
| User entered 'UN UNK 2015' | (b) (4), (b) (6) | 22 Sep 2020 16:20:01 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:25:14

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:19:48 |
| User entered '0' | (b) (4), (b) (6) | 22 Sep 2020 16:20:01 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:25:14

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:19:48 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 22 Sep 2020 16:20:01 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:25:14

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:19:48 |
| User entered empty. | (b) (4), (b) (6) | 22 Sep 2020 16:20:01 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:25:14

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:19:48 |
| User entered 'No (N)' | (b) (4), (b) (6) | 22 Sep 2020 16:20:01 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:25:14

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '2' | System | 22 Sep 2020 16:20:01 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:25:14

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 22 Sep 2020 16:20:01 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:25:14

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 22 Sep 2020 16:20:01 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:25:14

Name of Medication

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) | 25 Feb 2021 16:48:39 |
| User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: OTHER GYNECOLOGICALS, ATC: CONTRACEPTIVES FOR TOPICAL USE, ATC: INTRAUTERINE CONTRACEPTIVES, PRODUCT: INTRAUTERINE CONTRACEPTIVE DEVICE, PRODUCTSYNONYM: PARAGARD - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 21 Jan 2021 16:23:05 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | (b) (4) | 21 Jan 2021 16:23:05 |
| Data point term sent to Coder | System | 21 Jan 2021 16:21:53 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 21 Jan 2021 16:21:21 |
| Coding entries removed. | (b) (4), (b) (6) | 21 Jan 2021 16:21:21 |
| User entered 'paragard' reason for change: Data Entry Error | (b) (4), (b) (6) | 21 Jan 2021 16:21:21 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 18:19:48 |
| User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: OTHER GYNECOLOGICALS, ATC: CONTRACEPTIVES FOR TOPICAL USE, ATC: INTRAUTERINE CONTRACEPTIVES, PRODUCT: INTRAUTERINE CONTRACEPTIVE DEVICE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 22 Sep 2020 16:25:44 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | (b) (4) | 22 Sep 2020 16:25:44 |
| Data point term sent to Coder | System | 22 Sep 2020 16:24:40 |
| User entered 'Intrauterine Device' | (b) (4), (b) (6) | 22 Sep 2020 16:23:41 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:25:14

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:19:48 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 22 Sep 2020 16:23:41 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:25:14

[Indication](#)

| Audit | User | Time (GMT) |
|------------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:19:48 |
| User entered 'Contraception' | (b) (4), (b) (6) | 22 Sep 2020 16:23:41 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:25:14

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:19:48 |
| User entered 'I' | (b) (4), (b) (6) | 22 Sep 2020 16:23:41 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:25:14

[Dose unit](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) | 25 Feb 2021 16:48:45 |
| | (b) (4), (b) (6) | |
| User closed query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM). | (b) (4), (b) (6) | 12 Nov 2020 19:16:04 |
| Query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' answered with 'updated' (Site from DM). | (b) (4), (b) (6) | 10 Nov 2020 22:17:34 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 10 Nov 2020 22:17:27 |
| User entered 'Other (OTHER)' reason for change: Data Entry Error | (b) (4), (b) (6) | 10 Nov 2020 22:17:27 |
| User opened query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM). | (b) (4), (b) (6) | 01 Nov 2020 11:13:43 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 18:19:48 |
| User entered 'IU (IU)' | (b) (4), (b) (6) | 22 Sep 2020 16:23:41 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:25:14

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 16:48:47 |
| DataPoint Un-verified. | | 10 Nov 2020 22:17:27 |
| User entered 'TUD' reason for change: Data Entry Error | | 10 Nov 2020 22:17:27 |
| DataPoint Verified. | | 07 Oct 2020 18:19:48 |
| User entered empty. | | 22 Sep 2020 16:23:41 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:25:14

[Frequency](#)

| Audit | User | Time (GMT) |
|------------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:19:48 |
| User entered 'other (OTHER)' | (b) (4), (b) (6) | 22 Sep 2020 16:23:41 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:25:14

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:19:48 |
| User entered 'Continuous' | (b) (4), (b) (6) | 22 Sep 2020 16:23:41 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:25:14

[Route of administration](#)

| Audit | User | Time (GMT) |
|------------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:19:48 |
| User entered 'Other (OTHER)' | (b) (4), (b) (6) | 22 Sep 2020 16:23:41 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:25:14

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|-----------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:19:48 |
| User entered 'Intrauterine' | (b) (4), (b) (6) | 22 Sep 2020 16:23:41 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:19:48 |
| User entered 'UN UNK 2018' | (b) (4), (b) (6) | 22 Sep 2020 16:23:41 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:25:14

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:19:48 |
| User entered '0' | (b) (4), (b) (6) | 22 Sep 2020 16:23:41 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:25:14

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:19:48 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 22 Sep 2020 16:23:41 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:25:14

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:19:48 |
| User entered empty. | (b) (4), (b) (6) | 22 Sep 2020 16:23:41 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:25:14

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 18:19:48 |
| User entered 'No (N)' | (b) (4), (b) (6) | 22 Sep 2020 16:23:41 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:25:14

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 22 Sep 2020 16:23:41 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:25:14

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 22 Sep 2020 16:23:41 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:25:14

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 22 Sep 2020 16:23:41 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:25:14

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 02:51:30 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 16:49:18 |
| 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) | 21 Jan 2021 16:24:04 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 21 Jan 2021 16:24:04 |
| Data point term sent to Coder | System | 21 Jan 2021 16:22:55 |
| User entered 'influenza vaccine' | (b) (4), (b) (6) | 21 Jan 2021 16:22:08 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:25:14

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 02:51:30 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 16:49:18 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 21 Jan 2021 16:22:08 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:25:14

[Indication](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 02:51:30 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 16:49:18 |
| User entered 'influenza vaccine' | (b) (4), (b) (6) | 21 Jan 2021 16:22:08 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:25:14

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 02:51:30 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 16:49:18 |
| User entered '0.5' | (b) (4), (b) (6) | 21 Jan 2021 16:22:08 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:25:14

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 02:51:30 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 16:49:18 |
| User entered 'mL (mL)' | (b) (4), (b) (6) | 21 Jan 2021 16:22:08 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:25:14

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 02:51:30 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 16:49:18 |
| User entered empty. | (b) (4), (b) (6) | 21 Jan 2021 16:22:08 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:25:14

[Frequency](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 02:51:30 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 16:49:18 |
| User entered 'once (ONCE)' | (b) (4), (b) (6) | 21 Jan 2021 16:22:08 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:25:14

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 02:51:30 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 16:49:18 |
| User entered empty. | (b) (4), (b) (6) | 21 Jan 2021 16:22:08 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:25:14

[Route of administration](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 02:51:30 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 16:49:18 |
| User entered 'Intramuscular (INTRAMUSCULAR)' | (b) (4), (b) (6) | 21 Jan 2021 16:22:08 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:25:14

[If route of administration is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 02:51:30 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 16:49:18 |
| User entered empty. | (b) (4), (b) (6) | 21 Jan 2021 16:22:08 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 02:51:30 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 16:49:18 |
| User entered '09 Nov 2020' | (b) (4), (b) (6) | 21 Jan 2021 16:22:08 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:25:14

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 02:51:30 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 16:49:18 |
| User entered '0' | (b) (4), (b) (6) | 21 Jan 2021 16:22:08 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:25:14

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 02:51:30 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 16:49:18 |
| User entered 'No (N)' | (b) (4), (b) (6) | 21 Jan 2021 16:22:08 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:25:14

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 02:51:30 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 16:49:18 |
| User entered '09 Nov 2020' | (b) (4), (b) (6) | 21 Jan 2021 16:22:08 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:25:14

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 02:51:30 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 16:49:18 |
| User entered 'No (N)' | (b) (4), (b) (6) | 21 Jan 2021 16:22:08 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:25:14

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 02:51:30 |
| User entered empty. | System | 21 Jan 2021 16:22:08 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:25:14

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 02:51:30 |
| User entered empty. | System | 21 Jan 2021 16:22:08 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:25:14

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 02:51:30 |
| User entered empty. | System | 21 Jan 2021 16:22:08 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:25:14

Name of Medication

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 02:51:34 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 23 Mar 2021 06:11:38 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 23 Mar 2021 06:11:38 |
| Data point term sent to Coder | System | 19 Mar 2021 13:40:57 |
| Coding entries removed. | (b) (4), (b) (6) | 19 Mar 2021 13:40:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 16:49:18 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 22 Feb 2021 12:59:57 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 22 Feb 2021 12:59:57 |
| Data point term sent to Coder | System | 22 Feb 2021 12:59:30 |
| User entered 'zofran' | (b) (4), (b) (6) | 22 Feb 2021 12:59:06 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:25:14

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 02:51:34 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 16:49:18 |
| User entered 'No (N)' | (b) (4), (b) (6) | 22 Feb 2021 12:59:06 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:25:14

[Indication](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 02:51:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:17:29 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User closed query 'Per DM CLR: Please note, there is a medical condition if APPENDICITIS WITH APPENDECTOMY. Please confirm if this Con Med is given for this medical condition. Review and update Indication and ensure to reconcile with AE entries so there is an appropriate match. Else, clarify. ' (Site from DM). | (b) (4) (b) (4), (b) (6) | 22 Mar 2021 18:12:08 |
| Query 'Per DM CLR: Please note, there is a medical condition if APPENDICITIS WITH APPENDECTOMY. Please confirm if this Con Med is given for this medical condition. Review and update Indication and ensure to reconcile with AE entries so there is an appropriate match. Else, clarify. ' answered with 'updated ' (Site from DM). | (b) (4), (b) (6) | 19 Mar 2021 13:40:27 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 19 Mar 2021 13:40:22 |
| User entered 'NAUSEA (appendicitis)' reason for change: Data Entry Error | (b) (4), (b) (6) | 19 Mar 2021 13:40:22 |
| User opened query 'Per DM CLR: Please note, there is a medical condition if APPENDICITIS WITH APPENDECTOMY. Please confirm if this Con Med is given for this medical condition. Review and update Indication and ensure to reconcile with AE entries so there is an appropriate match. Else, clarify. ' (Site from DM). | (b) (4), (b) (6) | 03 Mar 2021 16:25:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 16:49:18 |
| User entered 'nausea' | (b) (4), (b) (6) | 22 Feb 2021 12:59:06 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:25:14

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 02:51:34 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 16:49:18 |
| User entered '4' | (b) (4), (b) (6) | 22 Feb 2021 12:59:06 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:25:14

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 02:51:34 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 16:49:18 |
| User entered 'mg (mg)' | (b) (4), (b) (6) | 22 Feb 2021 12:59:06 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:25:14

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 02:51:34 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 16:49:18 |
| User entered empty. | (b) (4), (b) (6) | 22 Feb 2021 12:59:06 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:25:14

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 02:51:34 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 16:49:18 |
| User entered 'as needed (PRN)' | (b) (4), (b) (6) | 22 Feb 2021 12:59:06 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:25:14

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 02:51:34 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 16:49:18 |
| User entered empty. | (b) (4), (b) (6) | 22 Feb 2021 12:59:06 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:25:14

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 02:51:34 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 16:49:18 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6) | 22 Feb 2021 12:59:06 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:25:14

[If route of administration is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 02:51:34 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 16:49:18 |
| User entered empty. | (b) (4), (b) (6) | 22 Feb 2021 12:59:06 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:25:14

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 02:51:34 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 16:49:18 |
| User entered '22 Dec 2020' | (b) (4), (b) (6) | 22 Feb 2021 12:59:06 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:25:14

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 02:51:34 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 16:49:18 |
| User entered '0' | (b) (4), (b) (6) | 22 Feb 2021 12:59:06 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:25:14

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 02:51:34 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 16:49:18 |
| User entered 'No (N)' | (b) (4), (b) (6) | 22 Feb 2021 12:59:06 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:25:14

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 02:51:34 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 16:49:18 |
| User entered '22 Dec 2020' | (b) (4), (b) (6) | 22 Feb 2021 12:59:06 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:25:14

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 02:51:34 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 16:49:18 |
| User entered 'No (N)' | (b) (4), (b) (6) | 22 Feb 2021 12:59:06 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:25:14

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 02:51:34 |
| User entered empty. | System | 22 Feb 2021 12:59:06 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:25:14

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 02:51:34 |
| User entered empty. | System | 22 Feb 2021 12:59:06 |

US3712094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:25:14

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 02:51:34 |
| User entered empty. | System | 22 Feb 2021 12:59:06 |

US3712094

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:25:14

[Were any concomitant procedures performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 10:21:14 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 16:49:24 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 21 Jan 2021 16:38:01 |

US3712094

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:25:14

Procedure/Surgery date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 19:11:03 |
| User entered '21 Dec 2020' | (b) (4), (b) (6) | 21 Jan 2021 16:38:15 |

US3712094

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:25:14

[Procedure/Surgery](#)

| Audit | User | Time (GMT) |
|-----------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 19:11:03 |
| User entered 'appendectomy' | (b) (4), (b) (6) | 21 Jan 2021 16:38:15 |

US3712094

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:25:14

[Indication](#)

| Audit | User | Time (GMT) |
|-----------------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 19:11:03 |
| User entered 'Adverse Event (AE)' | (b) (4), (b) (6) | 21 Jan 2021 16:38:15 |

US3712094

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:25:14

[If indication is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 19:11:03 |
| User entered empty. | (b) (4), (b) (6) | 21 Jan 2021 16:38:15 |

US3712094

Folder: SAE USA-US068-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:25:14

[SAEID](#)

| Audit | User | Time (GMT) |
|---------------------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 19:44:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Feb 2021 14:42:45 |
| User entered | System | 24 Feb 2021 14:41:48 |
| 'USA-US068-2021-MRNA-1273-P301000015' | | |

US3712094

Folder: SAE USA-US068-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:25:14

Serious

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 19:44:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Feb 2021 14:42:51 |
| User entered 'Yes (Y)' | System | 24 Feb 2021 14:41:48 |

US3712094

Folder: SAE USA-US068-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:25:14

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 19:44:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Feb 2021 14:42:51 |
| User entered 'No (N)' | System | 24 Feb 2021 14:41:48 |

US3712094

Folder: SAE USA-US068-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:25:14

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 19:44:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Feb 2021 14:42:51 |
| User entered 'No (N)' | System | 24 Feb 2021 14:41:48 |

US3712094

Folder: SAE USA-US068-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:25:14

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 19:44:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Feb 2021 14:42:51 |
| User entered 'Yes (Y)' | System | 24 Feb 2021 14:41:48 |

US3712094

Folder: SAE USA-US068-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:25:14

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 19:44:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Feb 2021 14:42:51 |
| User entered 'No (N)' | System | 24 Feb 2021 14:41:48 |

US3712094

Folder: SAE USA-US068-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:25:14

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 19:44:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Feb 2021 14:42:51 |
| User entered 'No (N)' | System | 24 Feb 2021 14:41:48 |

US3712094

Folder: SAE USA-US068-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:25:14

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 19:44:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Feb 2021 14:42:51 |
| User entered 'No (N)' | System | 24 Feb 2021 14:41:48 |

US3712094

Folder: SAE USA-US068-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:25:14

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 19:44:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Feb 2021 14:42:51 |
| User entered 'William' | System | 24 Feb 2021 14:41:48 |

US3712094

Folder: SAE USA-US068-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:25:14

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 19:44:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Feb 2021 14:42:51 |
| User entered 'Smith' | System | 24 Feb 2021 14:41:48 |

US3712094

Folder: SAE USA-US068-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:25:14

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|-------------------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:36:26 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 26 Feb 2021 14:23:23 |
| User entered empty. | System | 26 Feb 2021 14:22:54 |
| User entered '801 North Weisgarber' | (b) (4), (b) (6) | 25 Feb 2021 22:27:37 |

US3712094

Folder: SAE USA-US068-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:25:14

[Site Address: City](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:36:26 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 26 Feb 2021 14:23:23 |
| User entered empty. | System | 26 Feb 2021 14:22:54 |
| User entered 'Knoxville' | (b) (4), (b) (6) | 25 Feb 2021 22:27:37 |

US3712094

Folder: SAE USA-US068-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:25:14

[Site Address: State](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:36:26 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 26 Feb 2021 14:23:23 |
| User entered empty. | System | 26 Feb 2021 14:22:54 |
| User entered 'TN' | (b) (4), (b) (6) | 25 Feb 2021 22:27:37 |

US3712094

Folder: SAE USA-US068-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:25:14

Site Address: Postal Code

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:36:26 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 26 Feb 2021 14:23:23 |
| User entered (b) (4) | System | 26 Feb 2021 14:22:54 |
| Un-reviewed for Safety. | (b) (4), (b) (6) | 25 Feb 2021 22:27:37 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 25 Feb 2021 22:27:37 |
| User entered '37909' reason for change: Data Entry Error | (b) (4), (b) (6) | 25 Feb 2021 22:27:37 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 19:44:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Feb 2021 14:42:51 |
| User entered (b) (4) ' | System | 24 Feb 2021 14:41:48 |

US3712094

Folder: SAE USA-US068-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:25:14

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 26 Feb 2021 14:23:23 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 19:44:30 |
| User entered 'US' | System | 24 Feb 2021 14:43:06 |

US3712094

Folder: SAE USA-US068-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:25:14

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '4' | System | 30 Mar 2021 17:14:06 |
| User entered '3' | System | 22 Mar 2021 16:16:17 |
| User entered '2' | System | 26 Feb 2021 14:22:54 |
| User entered '1' | System | 24 Feb 2021 14:43:06 |

US3712094

Folder: SAE USA-US068-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:25:14

[SAEID](#)

| Audit | User | Time (GMT) |
|---------------------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 19:44:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Feb 2021 14:42:45 |
| User entered | | |
| 'USA-US068-2021-MRNA-1273-P301000015' | System | 24 Feb 2021 14:41:48 |

US3712094

Folder: SAE USA-US068-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:25:14

Serious

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 19:44:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Feb 2021 14:42:51 |
| User entered 'Yes (Y)' | System | 24 Feb 2021 14:41:48 |

US3712094

Folder: SAE USA-US068-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:25:14

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 19:44:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Feb 2021 14:42:51 |
| User entered 'No (N)' | System | 24 Feb 2021 14:41:48 |

US3712094

Folder: SAE USA-US068-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:25:14

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 19:44:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Feb 2021 14:42:51 |
| User entered 'No (N)' | System | 24 Feb 2021 14:41:48 |

US3712094

Folder: SAE USA-US068-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:25:14

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 19:44:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Feb 2021 14:42:51 |
| User entered 'Yes (Y)' | System | 24 Feb 2021 14:41:48 |

US3712094

Folder: SAE USA-US068-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:25:14

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 19:44:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Feb 2021 14:42:51 |
| User entered 'No (N)' | System | 24 Feb 2021 14:41:48 |

US3712094

Folder: SAE USA-US068-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:25:14

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 19:44:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Feb 2021 14:42:51 |
| User entered 'No (N)' | System | 24 Feb 2021 14:41:48 |

US3712094

Folder: SAE USA-US068-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:25:14

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 19:44:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Feb 2021 14:42:51 |
| User entered 'No (N)' | System | 24 Feb 2021 14:41:48 |

US3712094

Folder: SAE USA-US068-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:25:14

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 19:44:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Feb 2021 14:42:51 |
| User entered 'William' | System | 24 Feb 2021 14:41:48 |

US3712094

Folder: SAE USA-US068-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:25:14

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 19:44:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Feb 2021 14:42:51 |
| User entered 'Smith' | System | 24 Feb 2021 14:41:48 |

US3712094

Folder: SAE USA-US068-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:25:14

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|-------------------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:36:26 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 26 Feb 2021 14:23:23 |
| User entered empty. | System | 26 Feb 2021 14:22:54 |
| User entered '801 North Weisgarber' | (b) (4), (b) (6) | 25 Feb 2021 22:27:37 |

US3712094

Folder: SAE USA-US068-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:25:14

[Site Address: City](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:36:26 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 26 Feb 2021 14:23:23 |
| User entered empty. | System | 26 Feb 2021 14:22:54 |
| User entered 'Knoxville' | (b) (4), (b) (6) | 25 Feb 2021 22:27:37 |

US3712094

Folder: SAE USA-US068-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:25:14

[Site Address: State](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:36:26 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 26 Feb 2021 14:23:23 |
| User entered empty. | System | 26 Feb 2021 14:22:54 |
| User entered 'TN' | (b) (4), (b) (6) | 25 Feb 2021 22:27:37 |

US3712094

Folder: SAE USA-US068-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:25:14

Site Address: Postal Code

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:36:26 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 26 Feb 2021 14:23:23 |
| User entered (b) (4) | System | 26 Feb 2021 14:22:54 |
| Un-reviewed for Safety. | (b) (4), (b) (6) | 25 Feb 2021 22:27:37 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 25 Feb 2021 22:27:37 |
| User entered '37909' reason for change: Data Entry Error | (b) (4), (b) (6) | 25 Feb 2021 22:27:37 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 19:44:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Feb 2021 14:42:51 |
| User entered (b) (4) | System | 24 Feb 2021 14:41:48 |

US3712094

Folder: SAE USA-US068-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:25:14

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 26 Feb 2021 14:23:23 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 19:44:30 |
| User entered 'US' | System | 24 Feb 2021 14:43:06 |

US3712094

Folder: SAE USA-US068-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:25:14

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '4' | System | 30 Mar 2021 17:14:06 |
| User entered '3' | System | 22 Mar 2021 16:16:17 |
| User entered '2' | System | 26 Feb 2021 14:22:54 |
| User entered '1' | System | 24 Feb 2021 14:43:06 |

US3712094

Folder: SAE USA-US068-2021-MRNA-1273-P301000015

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:25:14

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 19:44:30 |
| User entered '24/Feb/2021 09:43' | System | 24 Feb 2021 14:43:06 |

US3712094

Folder: SAE USA-US068-2021-MRNA-1273-P301000015

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:25:14

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 26 Feb 2021 14:23:23 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 19:44:30 |
| User entered 'I' | (b) (4), (b) (6) | 24 Feb 2021 14:43:06 |

US3712094

Folder: SAE USA-US068-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:25:14

[SAEID](#)

| Audit | User | Time (GMT) |
|---------------------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 19:44:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Feb 2021 14:42:45 |
| User entered | | |
| 'USA-US068-2021-MRNA-1273-P301000015' | System | 24 Feb 2021 14:41:48 |

US3712094

Folder: SAE USA-US068-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:25:14

Serious

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 19:44:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Feb 2021 14:42:51 |
| User entered 'Yes (Y)' | System | 24 Feb 2021 14:41:48 |

US3712094

Folder: SAE USA-US068-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:25:14

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 19:44:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Feb 2021 14:42:51 |
| User entered 'No (N)' | System | 24 Feb 2021 14:41:48 |

US3712094

Folder: SAE USA-US068-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:25:14

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 19:44:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Feb 2021 14:42:51 |
| User entered 'No (N)' | System | 24 Feb 2021 14:41:48 |

US3712094

Folder: SAE USA-US068-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:25:14

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 19:44:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Feb 2021 14:42:51 |
| User entered 'Yes (Y)' | System | 24 Feb 2021 14:41:48 |

US3712094

Folder: SAE USA-US068-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:25:14

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 19:44:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Feb 2021 14:42:51 |
| User entered 'No (N)' | System | 24 Feb 2021 14:41:48 |

US3712094

Folder: SAE USA-US068-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:25:14

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 19:44:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Feb 2021 14:42:51 |
| User entered 'No (N)' | System | 24 Feb 2021 14:41:48 |

US3712094

Folder: SAE USA-US068-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:25:14

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 19:44:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Feb 2021 14:42:51 |
| User entered 'No (N)' | System | 24 Feb 2021 14:41:48 |

US3712094

Folder: SAE USA-US068-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:25:14

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 19:44:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Feb 2021 14:42:51 |
| User entered 'William' | System | 24 Feb 2021 14:41:48 |

US3712094

Folder: SAE USA-US068-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:25:14

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 19:44:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Feb 2021 14:42:51 |
| User entered 'Smith' | System | 24 Feb 2021 14:41:48 |

US3712094

Folder: SAE USA-US068-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:25:14

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|-------------------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:36:26 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 26 Feb 2021 14:23:23 |
| User entered empty. | System | 26 Feb 2021 14:22:54 |
| User entered '801 North Weisgarber' | (b) (4), (b) (6) | 25 Feb 2021 22:27:37 |

US3712094

Folder: SAE USA-US068-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:25:14

[Site Address: City](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:36:26 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 26 Feb 2021 14:23:23 |
| User entered empty. | System | 26 Feb 2021 14:22:54 |
| User entered 'Knoxville' | (b) (4), (b) (6) | 25 Feb 2021 22:27:37 |

US3712094

Folder: SAE USA-US068-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:25:14

[Site Address: State](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:36:26 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 26 Feb 2021 14:23:23 |
| User entered empty. | System | 26 Feb 2021 14:22:54 |
| User entered 'TN' | (b) (4), (b) (6) | 25 Feb 2021 22:27:37 |

US3712094

Folder: SAE USA-US068-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:25:14

Site Address: Postal Code

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:36:26 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 26 Feb 2021 14:23:23 |
| User entered (b) (4) | System | 26 Feb 2021 14:22:54 |
| Un-reviewed for Safety. | (b) (4), (b) (6) | 25 Feb 2021 22:27:37 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 25 Feb 2021 22:27:37 |
| User entered '37909' reason for change: Data Entry Error | (b) (4), (b) (6) | 25 Feb 2021 22:27:37 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 19:44:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Feb 2021 14:42:51 |
| User entered (b) (4) ' | System | 24 Feb 2021 14:41:48 |

US3712094

Folder: SAE USA-US068-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:25:14

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 26 Feb 2021 14:23:23 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 19:44:30 |
| User entered 'US' | System | 24 Feb 2021 14:43:06 |

US3712094

Folder: SAE USA-US068-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:25:14

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '4' | System | 30 Mar 2021 17:14:06 |
| User entered '3' | System | 22 Mar 2021 16:16:17 |
| User entered '2' | System | 26 Feb 2021 14:22:54 |
| User entered '1' | System | 24 Feb 2021 14:43:06 |

US3712094

Folder: SAE USA-US068-2021-MRNA-1273-P301000015

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:25:14

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:36:26 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered '26/Feb/2021 09:22' | (b) (4) System | 26 Feb 2021 14:22:54 |

US3712094

Folder: SAE USA-US068-2021-MRNA-1273-P301000015

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:25:14

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:36:26 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 26 Feb 2021 14:23:23 |
| User entered 'I' | (b) (4), (b) (6) | 26 Feb 2021 14:22:54 |

US3712094

Folder: SAE USA-US068-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:25:14

[SAEID](#)

| Audit | User | Time (GMT) |
|---------------------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 19:44:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Feb 2021 14:42:45 |
| User entered | System | 24 Feb 2021 14:41:48 |
| 'USA-US068-2021-MRNA-1273-P301000015' | | |

US3712094

Folder: SAE USA-US068-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:25:14

Serious

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 19:44:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Feb 2021 14:42:51 |
| User entered 'Yes (Y)' | System | 24 Feb 2021 14:41:48 |

US3712094

Folder: SAE USA-US068-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:25:14

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 19:44:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Feb 2021 14:42:51 |
| User entered 'No (N)' | System | 24 Feb 2021 14:41:48 |

US3712094

Folder: SAE USA-US068-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:25:14

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 19:44:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Feb 2021 14:42:51 |
| User entered 'No (N)' | System | 24 Feb 2021 14:41:48 |

US3712094

Folder: SAE USA-US068-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:25:14

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 19:44:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Feb 2021 14:42:51 |
| User entered 'Yes (Y)' | System | 24 Feb 2021 14:41:48 |

US3712094

Folder: SAE USA-US068-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:25:14

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 19:44:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Feb 2021 14:42:51 |
| User entered 'No (N)' | System | 24 Feb 2021 14:41:48 |

US3712094

Folder: SAE USA-US068-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:25:14

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 19:44:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Feb 2021 14:42:51 |
| User entered 'No (N)' | System | 24 Feb 2021 14:41:48 |

US3712094

Folder: SAE USA-US068-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:25:14

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 19:44:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Feb 2021 14:42:51 |
| User entered 'No (N)' | System | 24 Feb 2021 14:41:48 |

US3712094

Folder: SAE USA-US068-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:25:14

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 19:44:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Feb 2021 14:42:51 |
| User entered 'William' | System | 24 Feb 2021 14:41:48 |

US3712094

Folder: SAE USA-US068-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:25:14

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 19:44:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Feb 2021 14:42:51 |
| User entered 'Smith' | System | 24 Feb 2021 14:41:48 |

US3712094

Folder: SAE USA-US068-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:25:14

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|-------------------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:36:26 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 26 Feb 2021 14:23:23 |
| User entered empty. | System | 26 Feb 2021 14:22:54 |
| User entered '801 North Weisgarber' | (b) (4), (b) (6) | 25 Feb 2021 22:27:37 |

US3712094

Folder: SAE USA-US068-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:25:14

[Site Address: City](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:36:26 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 26 Feb 2021 14:23:23 |
| User entered empty. | System | 26 Feb 2021 14:22:54 |
| User entered 'Knoxville' | (b) (4), (b) (6) | 25 Feb 2021 22:27:37 |

US3712094

Folder: SAE USA-US068-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:25:14

[Site Address: State](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:36:26 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 26 Feb 2021 14:23:23 |
| User entered empty. | System | 26 Feb 2021 14:22:54 |
| User entered 'TN' | (b) (4), (b) (6) | 25 Feb 2021 22:27:37 |

US3712094

Folder: SAE USA-US068-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:25:14

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:36:26 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 26 Feb 2021 14:23:23 |
| User entered (b) (4) | System | 26 Feb 2021 14:22:54 |
| Un-reviewed for Safety. | (b) (4), (b) (6) | 25 Feb 2021 22:27:37 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 25 Feb 2021 22:27:37 |
| User entered '37909' reason for change: Data Entry Error | (b) (4), (b) (6) | 25 Feb 2021 22:27:37 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 19:44:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Feb 2021 14:42:51 |
| User entered (b) (4) | System | 24 Feb 2021 14:41:48 |

US3712094

Folder: SAE USA-US068-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:25:14

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 26 Feb 2021 14:23:23 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 19:44:30 |
| User entered 'US' | System | 24 Feb 2021 14:43:06 |

US3712094

Folder: SAE USA-US068-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:25:14

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '4' | System | 30 Mar 2021 17:14:06 |
| User entered '3' | System | 22 Mar 2021 16:16:17 |
| User entered '2' | System | 26 Feb 2021 14:22:54 |
| User entered '1' | System | 24 Feb 2021 14:43:06 |

US3712094

Folder: SAE USA-US068-2021-MRNA-1273-P301000015

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:25:14

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:36:26 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered '22/Mar/2021 12:16' | (b) (4) System | 22 Mar 2021 16:16:17 |

US3712094

Folder: SAE USA-US068-2021-MRNA-1273-P301000015

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:25:14

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:36:26 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 30 Mar 2021 17:13:54 |
| User entered 'I' | (b) (4), (b) (6) | 22 Mar 2021 16:16:17 |

US3712094

Folder: SAE USA-US068-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:25:14

[SAEID](#)

| Audit | User | Time (GMT) |
|---------------------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 19:44:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Feb 2021 14:42:45 |
| User entered | | |
| 'USA-US068-2021-MRNA-1273-P301000015' | System | 24 Feb 2021 14:41:48 |

US3712094

Folder: SAE USA-US068-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:25:14

Serious

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 19:44:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Feb 2021 14:42:51 |
| User entered 'Yes (Y)' | System | 24 Feb 2021 14:41:48 |

US3712094

Folder: SAE USA-US068-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:25:14

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 19:44:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Feb 2021 14:42:51 |
| User entered 'No (N)' | System | 24 Feb 2021 14:41:48 |

US3712094

Folder: SAE USA-US068-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:25:14

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 19:44:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Feb 2021 14:42:51 |
| User entered 'No (N)' | System | 24 Feb 2021 14:41:48 |

US3712094

Folder: SAE USA-US068-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:25:14

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 19:44:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Feb 2021 14:42:51 |
| User entered 'Yes (Y)' | System | 24 Feb 2021 14:41:48 |

US3712094

Folder: SAE USA-US068-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:25:14

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 19:44:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Feb 2021 14:42:51 |
| User entered 'No (N)' | System | 24 Feb 2021 14:41:48 |

US3712094

Folder: SAE USA-US068-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:25:14

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 19:44:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Feb 2021 14:42:51 |
| User entered 'No (N)' | System | 24 Feb 2021 14:41:48 |

US3712094

Folder: SAE USA-US068-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:25:14

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 19:44:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Feb 2021 14:42:51 |
| User entered 'No (N)' | System | 24 Feb 2021 14:41:48 |

US3712094

Folder: SAE USA-US068-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:25:14

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 19:44:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Feb 2021 14:42:51 |
| User entered 'William' | System | 24 Feb 2021 14:41:48 |

US3712094

Folder: SAE USA-US068-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:25:14

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 19:44:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Feb 2021 14:42:51 |
| User entered 'Smith' | System | 24 Feb 2021 14:41:48 |

US3712094

Folder: SAE USA-US068-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:25:14

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|-------------------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:36:26 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 26 Feb 2021 14:23:23 |
| User entered empty. | System | 26 Feb 2021 14:22:54 |
| User entered '801 North Weisgarber' | (b) (4), (b) (6) | 25 Feb 2021 22:27:37 |

US3712094

Folder: SAE USA-US068-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:25:14

[Site Address: City](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:36:26 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 26 Feb 2021 14:23:23 |
| User entered empty. | System | 26 Feb 2021 14:22:54 |
| User entered 'Knoxville' | (b) (4), (b) (6) | 25 Feb 2021 22:27:37 |

US3712094

Folder: SAE USA-US068-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:25:14

[Site Address: State](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:36:26 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 26 Feb 2021 14:23:23 |
| User entered empty. | System | 26 Feb 2021 14:22:54 |
| User entered 'TN' | (b) (4), (b) (6) | 25 Feb 2021 22:27:37 |

US3712094

Folder: SAE USA-US068-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:25:14

Site Address: Postal Code

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:36:26 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 26 Feb 2021 14:23:23 |
| User entered (b) (4) | System | 26 Feb 2021 14:22:54 |
| Un-reviewed for Safety. | (b) (4), (b) (6) | 25 Feb 2021 22:27:37 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 25 Feb 2021 22:27:37 |
| User entered '37909' reason for change: Data Entry Error | (b) (4), (b) (6) | 25 Feb 2021 22:27:37 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 19:44:30 |
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Feb 2021 14:42:51 |
| User entered (b) (4) ' | System | 24 Feb 2021 14:41:48 |

US3712094

Folder: SAE USA-US068-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:25:14

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 26 Feb 2021 14:23:23 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 19:44:30 |
| User entered 'US' | System | 24 Feb 2021 14:43:06 |

US3712094

Folder: SAE USA-US068-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:25:14

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '4' | System | 30 Mar 2021 17:14:06 |
| User entered '3' | System | 22 Mar 2021 16:16:17 |
| User entered '2' | System | 26 Feb 2021 14:22:54 |
| User entered '1' | System | 24 Feb 2021 14:43:06 |

US3712094

Folder: SAE USA-US068-2021-MRNA-1273-P301000015

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:25:14

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:36:26 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered '30/Mar/2021 12:14' | (b) (4) System | 30 Mar 2021 17:14:06 |

US3712094

Folder: SAE USA-US068-2021-MRNA-1273-P301000015

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:25:14

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 20:36:26 |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:19:21 |
| User entered 'I' | (b) (4) (b) (4), (b) (6) | 30 Mar 2021 17:14:06 |