

US3172224 (Prod: Suncoast Research Group LLC - ERN-PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 15:33:17

All time stamps listed in this document are displayed in GMT

US3172224

Form: Participant Creation

Data signed: (b) (4) 17 Feb 2021 13:11:37

Generated On: 09 Jun 2021 15:33:17

Participant ID

US3172224

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

US3172224

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 13:11:38

Generated On: 09 Jun 2021 15:33:17

Was this visit performed? Yes ☒
No ☐

Visit date (dd MMM yyyy) 19 AUG 2020

Was visit performed at the participant's home or at the clinic? Home ☐
Clinic ☒

Folder OID SCRN

US3172224

Folder: Screening

Form: Demographics

Data signed: (b) (4) 17 Feb 2021 13:11:38

Generated On: 09 Jun 2021 15:33:17

| | |
|---|--|
| Date of Birth (MMM yyyy) | (b) (6) 1970 |
| Age | 50 |
| Age Units | YEARS |
| Age (Derived) | 50 |
| Sex | Female <input type="radio"/> Male <input checked="" type="radio"/> |
| Ethnicity | Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input 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 |

US3172224

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 17 Feb 2021 13:11:38

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Date of Informed Consent (*dd MMM yyyy*) 19 AUG 2020

Month and Year of Informed Consent (derived) AUG 2020

Year of Informed Consent (derived) 2020

Protocol Version

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

Was participant enrolled in the study?

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

If No, indicate reason for screen fail

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

If reason for screen fail is Other, specify _____

Was this participant screened previously?

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

If Yes, previous participant number _____

Enrollment Trigger 1

US3172224

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 17 Feb 2021 13:11:38

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 17 Feb 2021 13:11:38

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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) 17 Feb 2021 13:11:38

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| | |
|---|--|
| Condition | HYPERMETROPHIA |
| Start date (dd MMM yyyy) | UN UNK 2000 |
| 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 2000 |
| Start Year (derived) | 2000 |
| Stop Month and Year (derived) | _____ |
| Stop Year (derived) | _____ |

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 17 Feb 2021 13:11:38

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

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 17 Feb 2021 13:11:38

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| | |
|---|--|
| Condition | LEFT KIDNEY STONES |
| Start date (dd MMM yyyy) | UN UNK 2015 |
| 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 2015 |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 2015 |
| Start Year (derived) | 2015 |
| Stop Month and Year (derived) | JAN 2015 |
| Stop Year (derived) | 2015 |

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 17 Feb 2021 13:11:38

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| | |
|---|--|
| Condition | RIGHT ELBOW FRACTURE |
| Start date (dd MMM yyyy) | UN UNK 2015 |
| 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 2015 |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 2015 |
| Start Year (derived) | 2015 |
| Stop Month and Year (derived) | JAN 2015 |
| Stop Year (derived) | 2015 |

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 17 Feb 2021 13:11:38

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

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 17 Feb 2021 13:11:38

Generated On: 09 Jun 2021 15:33:17

| | |
|-------------------------------------|--------------------------------------|
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 19 AUG 2020 |
| Time of assessment (00:00-23:59) | 13:55 (24 HR) |
| Vital Signs Date and Time (derived) | 19 AUG 2020 13:55 |
| Height (xxx.x) | 173.3 cm |
| Weight (xxx.x) | 72.2 kg |
| BMI (xxx.x) | 24.04031 kg/m ² |
| BMI units | KG/M2 |
| Temperature (xxx.x) | ND - Not Done |
| Route of measurement | Oral <input type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | ND - Not Done |
| Pulse units | BPM |
| Respiratory Rate (xxx) | ND - Not Done |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | ND - Not Done |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | ND - Not Done |
| Diastolic Blood Pressure units | MMHG |
| Height (derived) | |
| Weight (derived) | |

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 13:11:38

Generated On: 09 Jun 2021 15:33:17

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.

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 17 Feb 2021 13:11:38

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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) 17 Feb 2021 13:11:38

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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) | True |
| Resides in a single family home (i.e., detached housing) | False |
| Other | False |
| Specify | |

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 13:11:38

Generated On: 09 Jun 2021 15:33:17

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

| | |
|--------------------------|-------------|
| Visit date (dd MMM yyyy) | 19 AUG 2020 |
|--------------------------|-------------|

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

| | |
|------------|--------|
| Folder OID | VISIT1 |
|------------|--------|

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 17 Feb 2021 13:11:38

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

What was the participant's randomization number? 106115

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 17 Feb 2021 13:11:38

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

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 17 Feb 2021 13:11:38

Generated On: 09 Jun 2021 15:33:17

| | |
|-------------------------------------|--|
| Height | ND - Not Done |
| Weight | ND - Not Done |
| Timepoint | Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/> |
| Were vital signs assessed? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 19 AUG 2020 |
| Time of assessment (00:00-23:59) | 13:55 (24 HR) |
| Vital Signs Date and Time (derived) | 19 AUG 2020 13:55 |
| 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) | 84 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) | 85 mmHg |
| Diastolic Blood Pressure units | MMHG |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 17 Feb 2021 13:11:38

Generated On: 09 Jun 2021 15:33:17

| | |
|-------------------------------------|--|
| Height | ND - Not Done |
| Weight | ND - Not Done |
| Timepoint | Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/> |
| Were vital signs assessed? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 19 AUG 2020 |
| Time of assessment (00:00-23:59) | 17:11 (24 HR) |
| Vital Signs Date and Time (derived) | 19 AUG 2020 17:11 |
| Temperature (xxx.x) | 36.6 C |
| Route of measurement | Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 74 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 14 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 119 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 78 mmHg |
| Diastolic Blood Pressure units | MMHG |

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 13:11:38

Generated On: 09 Jun 2021 15:33:17

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 AUG 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 17 Feb 2021 13:11:38

Generated On: 09 Jun 2021 15:33:17

Was study treatment given? Yes ☒
No ☐

If No, reason not given

Participant declined due to Adverse Event ☐
Physician withheld dose due to Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by Participant ☐
Confirmed COVID-19 ☐
Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

What was the treatment time? (00:00-23:59) 16:41 (24 HR)

Treatment Date and Time (derived) 19 AUG 2020 16:41

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 17 Feb 2021 13:11:38

Generated On: 09 Jun 2021 15:33:17

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

| | |
|-------------------------------|-------------|
| Collection date (dd MMM yyyy) | 19 AUG 2020 |
|-------------------------------|-------------|

| | |
|-------------------------------|---------------|
| Collection time (00:00-23:59) | 16:06 (24 HR) |
|-------------------------------|---------------|

| | |
|------------------------------------|-------------------|
| Collection date and time (derived) | 19 AUG 2020 16:06 |
|------------------------------------|-------------------|

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 17 Feb 2021 13:11:38

Generated On: 09 Jun 2021 15:33:17

| | | | |
|-------------------------------|---------------------------|---------------------------------|------------------------------------|
| Collection date (dd MMM yyyy) | | | 19 AUG 2020 |
| Lab Test | Was the sample collected? | Collection time (00:00 - 23:59) | Collection date and time (derived) |
| Nasopharyngeal Swab 1 | Yes | 16:02 | 19 AUG 2020 16:02 |
| Nasopharyngeal Swab 2 | No | | |

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:11:38

Generated On: 09 Jun 2021 15:33:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

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

98.3 °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

19 AUG 2020 17:28

PC Open Date & Time

19 AUG 2020 17:01

PC Close Date & Time

19 AUG 2020 19:31

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 99.0 °F

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

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

| | |
|----------------------|-------------------|
| PC Time Stamp | 19 AUG 2020 20:27 |
| PC Open Date & Time | 19 AUG 2020 20:26 |
| PC Close Date & Time | 20 AUG 2020 11:59 |

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:33:17

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

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

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

| | |
|----------------------|-------------------|
| PC Time Stamp | 20 AUG 2020 14:24 |
| PC Open Date & Time | 20 AUG 2020 12:00 |
| PC Close Date & Time | 21 AUG 2020 11:59 |

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:33:17

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

98.3 °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

21 AUG 2020 14:14

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:33:17

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

98.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 AUG 2020 14:23

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:33:17

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

23 AUG 2020 15:40

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 AUG 2020 14:47

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:33:17

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

98.4 °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

25 AUG 2020 18:06

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

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 AUG 2020 17:29

PC Open Date & Time

19 AUG 2020 17:01

PC Close Date & Time

19 AUG 2020 19:31

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

19 AUG 2020 20:28

PC Open Date & Time

19 AUG 2020 20:26

PC Close Date & Time

20 AUG 2020 11:59

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

20 AUG 2020 14:24

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:33:17

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 AUG 2020 14:14

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

22 AUG 2020 14:24

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:33:17

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 AUG 2020 15:41

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

24 AUG 2020 14:47

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:33:17

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 AUG 2020 18:06

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3172224

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

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 ☐

US3172224

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 19 AUG 2020 17:29 |
| PC Open Date & Time | 19 AUG 2020 17:01 |
| PC Close Date & Time | 19 AUG 2020 19:31 |

US3172224

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

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 ☐

US3172224

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 19 AUG 2020 20:27 |
| PC Open Date & Time | 19 AUG 2020 20:26 |
| PC Close Date & Time | 20 AUG 2020 11:59 |

US3172224

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:33:17

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 ☒

US3172224

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:33:17

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 20 AUG 2020 14:25 |
| PC Open Date & Time | 20 AUG 2020 12:00 |
| PC Close Date & Time | 21 AUG 2020 11:59 |

US3172224

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:33:17

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

48 of 2066

EAB) (1725)

US3172224

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:33:17

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 21 AUG 2020 14:15 |
| PC Open Date & Time | 21 AUG 2020 12:00 |
| PC Close Date & Time | 22 AUG 2020 11:59 |

US3172224

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

50 of 2066

US3172224

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:33:17

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 22 AUG 2020 14:24 |
| PC Open Date & Time | 22 AUG 2020 12:00 |
| PC Close Date & Time | 23 AUG 2020 11:59 |

US3172224

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:33:17

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

52 of 2066

EAB) (1725)

US3172224

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:33:17

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 23 AUG 2020 15:41 |
| PC Open Date & Time | 23 AUG 2020 12:00 |
| PC Close Date & Time | 24 AUG 2020 11:59 |

US3172224

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

54 of 2066

EAB) (1725)

US3172224

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:33:17

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 24 AUG 2020 14:48 |
| PC Open Date & Time | 24 AUG 2020 12:00 |
| PC Close Date & Time | 25 AUG 2020 11:59 |

US3172224

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

56 of 2066

EAB) (1725)

US3172224

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:33:17

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 25 AUG 2020 18:06 |
| PC Open Date & Time | 25 AUG 2020 12:00 |
| PC Close Date & Time | 26 AUG 2020 11:59 |

US3172224

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:11:38

Generated On: 09 Jun 2021 15:33:17

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 26 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3172224

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:11:38

Generated On: 09 Jun 2021 15:33:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172224

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:11:37

Generated On: 09 Jun 2021 15:33:17

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3172224

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:11:37

Generated On: 09 Jun 2021 15:33:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172224

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:11:38

Generated On: 09 Jun 2021 15:33:17

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3172224

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:11:38

Generated On: 09 Jun 2021 15:33:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172224

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 13:11:38

Generated On: 09 Jun 2021 15:33:17

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 16 SEP 2020 |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/> |
| | Clinic <input checked="" type="radio"/> |
| Folder OID | VISIT2 |

US3172224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 17 Feb 2021 13:11:38

Generated On: 09 Jun 2021 15:33:17

| | |
|-------------------------------------|---|
| 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) | 16 SEP 2020 |
| Time of assessment (00:00-23:59) | 14:25 (24 HR) |
| Vital Signs Date and Time (derived) | 16 SEP 2020 14:25 |
| 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) | 95 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 16 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 91 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 75 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3172224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 17 Feb 2021 13:11:38

Generated On: 09 Jun 2021 15:33:17

| | |
|-------------------------------------|---|
| 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) | 16 SEP 2020 |
| Time of assessment (00:00-23:59) | 15:58 (24 HR) |
| Vital Signs Date and Time (derived) | 16 SEP 2020 15:58 |
| Temperature (xxx.x) | 37.1 C |
| Route of measurement | Oral <input checked="" type="checkbox"/> |
| | Axillary <input type="checkbox"/> |
| | Other <input type="checkbox"/> |
| If Other, specify | |
| Pulse (xxx) | 91 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 14 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 121 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 76 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3172224

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 13:11:38

Generated On: 09 Jun 2021 15:33:17

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 SEP 2020

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

US3172224

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 17 Feb 2021 13:11:38

Generated On: 09 Jun 2021 15:33:17

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) 16 SEP 2020

What was the treatment time? (00:00-23:59) 15:28 (24 HR)

Treatment Date and Time (derived) 16 SEP 2020 15:28

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

US3172224

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 17 Feb 2021 13:11:38

Generated On: 09 Jun 2021 15:33:17

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

| | |
|-------------------------------|-------------|
| Collection date (dd MMM yyyy) | 16 SEP 2020 |
|-------------------------------|-------------|

| | |
|-------------------------------|---------------|
| Collection time (00:00-23:59) | 15:17 (24 HR) |
|-------------------------------|---------------|

| | |
|------------------------------------|-------------------|
| Collection date and time (derived) | 16 SEP 2020 15:17 |
|------------------------------------|-------------------|

US3172224

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 17 Feb 2021 13:11:38

Generated On: 09 Jun 2021 15:33:17

| | | | |
|-------------------------------|---------------------------|---------------------------------|------------------------------------|
| Collection date (dd MMM yyyy) | | | 16 SEP 2020 |
| Lab Test | Was the sample collected? | Collection time (00:00 - 23:59) | Collection date and time (derived) |
| Nasopharyngeal Swab 1 | Yes | 15:13 | 16 SEP 2020 15:13 |
| Nasopharyngeal Swab 2 | Yes | 15:13 | 16 SEP 2020 15:13 |

US3172224

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:11:38

Generated On: 09 Jun 2021 15:33:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

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

98.9 °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

16 SEP 2020 15:58

PC Open Date & Time

16 SEP 2020 15:48

PC Close Date & Time

16 SEP 2020 18:18

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

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 | 16 SEP 2020 19:34 |
| PC Open Date & Time | 16 SEP 2020 19:13 |
| PC Close Date & Time | 17 SEP 2020 11:59 |

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:33:17

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

98.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 SEP 2020 12:03

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:33:17

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

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 SEP 2020 12:08

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:33:17

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

98.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 SEP 2020 16:33

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:33:17

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

98.4 °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 SEP 2020 12:06

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 SEP 2020 12:51

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:33:17

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

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

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

| | |
|----------------------|-------------------|
| PC Time Stamp | 22 SEP 2020 15:53 |
| PC Open Date & Time | 22 SEP 2020 12:00 |
| PC Close Date & Time | 23 SEP 2020 11:59 |

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

DAY 8

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °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

23 SEP 2020 12:34

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

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

16 SEP 2020 15:58

PC Open Date & Time

16 SEP 2020 15:48

PC Close Date & Time

16 SEP 2020 18:18

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

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

16 SEP 2020 19:34

PC Open Date & Time

16 SEP 2020 19:13

PC Close Date & Time

17 SEP 2020 11:59

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:33:17

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

17 SEP 2020 12:03

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:33:17

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

18 SEP 2020 12:08

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:33:17

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

19 SEP 2020 16:34

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:33:17

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

20 SEP 2020 12:07

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:33:17

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

21 SEP 2020 12:51

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:33:17

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

22 SEP 2020 15:53

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3172224

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

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 ☐

US3172224

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 16 SEP 2020 15:58 |
| PC Open Date & Time | 16 SEP 2020 15:48 |
| PC Close Date & Time | 16 SEP 2020 18:18 |

US3172224

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

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 ☐

US3172224

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 16 SEP 2020 19:34 |
| PC Open Date & Time | 16 SEP 2020 19:13 |
| PC Close Date & Time | 17 SEP 2020 11:59 |

US3172224

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:33:17

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 ☒

US3172224

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:33:17

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 17 SEP 2020 12:03 |
| PC Open Date & Time | 17 SEP 2020 12:00 |
| PC Close Date & Time | 18 SEP 2020 11:59 |

US3172224

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3172224

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:33:17

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 18 SEP 2020 12:08 |
| PC Open Date & Time | 18 SEP 2020 12:00 |
| PC Close Date & Time | 19 SEP 2020 11:59 |

US3172224

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:33:17

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 ☒

US3172224

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:33:17

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 19 SEP 2020 16:34 |
| PC Open Date & Time | 19 SEP 2020 12:00 |
| PC Close Date & Time | 20 SEP 2020 11:59 |

US3172224

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:33:17

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 ☒

US3172224

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:33:17

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 20 SEP 2020 12:07 |
| PC Open Date & Time | 20 SEP 2020 12:00 |
| PC Close Date & Time | 21 SEP 2020 11:59 |

US3172224

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:33:17

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 ☒

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EAB) (1725)

US3172224

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:33:17

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 21 SEP 2020 12:52 |
| PC Open Date & Time | 21 SEP 2020 12:00 |
| PC Close Date & Time | 22 SEP 2020 11:59 |

US3172224

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:33:17

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 22 SEP 2020 15:53 |
| PC Open Date & Time | 22 SEP 2020 12:00 |
| PC Close Date & Time | 23 SEP 2020 11:59 |

US3172224

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:33:17

| | |
|---|--|
| TIMEPOINT | DAY 8 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| PC Time stamp | 23 SEP 2020 12:34 |
| PC Open Date & Time | 23 SEP 2020 12:00 |
| PC Close Date & Time | 24 SEP 2020 11:59 |

US3172224

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:11:38

Generated On: 09 Jun 2021 15:33:17

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 23 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3172224

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:11:38

Generated On: 09 Jun 2021 15:33:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172224

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:11:38

Generated On: 09 Jun 2021 15:33:17

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 30 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3172224

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:11:38

Generated On: 09 Jun 2021 15:33:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172224

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:11:38

Generated On: 09 Jun 2021 15:33:17

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 07 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3172224

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:11:38

Generated On: 09 Jun 2021 15:33:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172224

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 13:11:47

Generated On: 09 Jun 2021 15:33:17

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

| | |
|--------------------------|-------------|
| Visit date (dd MMM yyyy) | 14 OCT 2020 |
|--------------------------|-------------|

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

| | |
|------------|--------|
| Folder OID | VISIT3 |
|------------|--------|

US3172224

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 17 Feb 2021 13:11:47

Generated On: 09 Jun 2021 15:33:17

| | |
|-------------------------------------|---------------------------------------|
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 14 OCT 2020 |
| Time of assessment (00:00-23:59) | 14:19 (24 HR) |
| Vital Signs Date and Time (derived) | 14 OCT 2020 14:19 |
| 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) | 92 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 18 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 116 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 79 mmHg |
| Diastolic Blood Pressure units | MMHG |
| Height (derived) | |
| Weight (derived) | |

US3172224

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 13:11:38

Generated On: 09 Jun 2021 15:33:17

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.

US3172224

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 17 Feb 2021 13:11:38

Generated On: 09 Jun 2021 15:33:17

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

| | |
|-------------------------------|-------------|
| Collection date (dd MMM yyyy) | 14 OCT 2020 |
|-------------------------------|-------------|

| | |
|-------------------------------|---------------|
| Collection time (00:00-23:59) | 14:41 (24 HR) |
|-------------------------------|---------------|

| | |
|------------------------------------|-------------------|
| Collection date and time (derived) | 14 OCT 2020 14:41 |
|------------------------------------|-------------------|

US3172224

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:11:38

Generated On: 09 Jun 2021 15:33:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 OCT 2020 06:07:59

Patient Cloud Open Date & Time

19 OCT 2020 00:01

Patient Cloud Close Date & Time

23 OCT 2020 23:59

US3172224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 OCT 2020 05:57:15

Patient Cloud Open Date & Time

26 OCT 2020 00:01

Patient Cloud Close Date & Time

30 OCT 2020 23:59

US3172224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 NOV 2020 06:06:18

Patient Cloud Open Date & Time

02 NOV 2020 00:01

Patient Cloud Close Date & Time

06 NOV 2020 23:59

US3172224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 NOV 2020 06:20:50

Patient Cloud Open Date & Time

16 NOV 2020 00:01

Patient Cloud Close Date & Time

20 NOV 2020 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

| TIMEPOINT | DAY 96 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> 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 | 23 NOV 2020 06:03:48 |
| Patient Cloud Open Date & Time | 20 NOV 2020 00:01 |
| Patient Cloud Close Date & Time | 24 NOV 2020 23:59 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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

27 NOV 2020 01:37:28

Patient Cloud Open Date & Time

27 NOV 2020 00:01

Patient Cloud Close Date & Time

01 DEC 2020 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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

05 DEC 2020 07:56:59

Patient Cloud Open Date & Time

04 DEC 2020 00:01

Patient Cloud Close Date & Time

08 DEC 2020 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

| 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 | 11 DEC 2020 05:55:59 |
| Patient Cloud Open Date & Time | 11 DEC 2020 00:01 |
| Patient Cloud Close Date & Time | 15 DEC 2020 23:59 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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

18 DEC 2020 05:52:57

Patient Cloud Open Date & Time

18 DEC 2020 00:01

Patient Cloud Close Date & Time

22 DEC 2020 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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

25 DEC 2020 08:59:40

Patient Cloud Open Date & Time

25 DEC 2020 00:01

Patient Cloud Close Date & Time

29 DEC 2020 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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

01 JAN 2021 00:15:29

Patient Cloud Open Date & Time

01 JAN 2021 00:01

Patient Cloud Close Date & Time

05 JAN 2021 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

| TIMEPOINT | DAY 145 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input 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 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"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 08 JAN 2021 05:53:48 |
| Patient Cloud Open Date & Time | 08 JAN 2021 00:01 |
| Patient Cloud Close Date & Time | 12 JAN 2021 23:59 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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

15 JAN 2021 06:07:35

Patient Cloud Open Date & Time

15 JAN 2021 00:01

Patient Cloud Close Date & Time

19 JAN 2021 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

| 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 <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 checked="" type="radio"/> Yes <input type="radio"/> |
| Date and time of submission | 22 JAN 2021 05:53:41 |
| Patient Cloud Open Date & Time | 22 JAN 2021 00:01 |
| Patient Cloud Close Date & Time | 26 JAN 2021 23:59 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

| TIMEPOINT | DAY 166 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="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 | 29 JAN 2021 09:24:20 |
| Patient Cloud Open Date & Time | 29 JAN 2021 00:01 |
| Patient Cloud Close Date & Time | 02 FEB 2021 23:59 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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

05 FEB 2021 06:30:53

Patient Cloud Open Date & Time

05 FEB 2021 00:01

Patient Cloud Close Date & Time

09 FEB 2021 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

| TIMEPOINT | DAY 180 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input 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 | 12 FEB 2021 06:41:15 |
| Patient Cloud Open Date & Time | 12 FEB 2021 00:01 |
| Patient Cloud Close Date & Time | 16 FEB 2021 23:59 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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

21 FEB 2021 12:00:25

Patient Cloud Open Date & Time

19 FEB 2021 00:01

Patient Cloud Close Date & Time

23 FEB 2021 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

| TIMEPOINT | DAY 194 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input 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 | 26 FEB 2021 05:30:22 |
| Patient Cloud Open Date & Time | 26 FEB 2021 00:01 |
| Patient Cloud Close Date & Time | 02 MAR 2021 23:59 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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

05 MAR 2021 06:07:40

Patient Cloud Open Date & Time

05 MAR 2021 00:01

Patient Cloud Close Date & Time

09 MAR 2021 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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

12 MAR 2021 05:45:46

Patient Cloud Open Date & Time

12 MAR 2021 00:01

Patient Cloud Close Date & Time

16 MAR 2021 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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

19 MAR 2021 05:28:12

Patient Cloud Open Date & Time

19 MAR 2021 00:01

Patient Cloud Close Date & Time

23 MAR 2021 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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

26 MAR 2021 06:39:49

Patient Cloud Open Date & Time

26 MAR 2021 00:01

Patient Cloud Close Date & Time

30 MAR 2021 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 APR 2021 06:28:30

Patient Cloud Open Date & Time

02 APR 2021 00:01

Patient Cloud Close Date & Time

06 APR 2021 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 APR 2021 06:08:51

Patient Cloud Open Date & Time

09 APR 2021 00:01

Patient Cloud Close Date & Time

13 APR 2021 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 APR 2021 06:02:59

Patient Cloud Open Date & Time

16 APR 2021 00:01

Patient Cloud Close Date & Time

20 APR 2021 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 APR 2021 06:06:34

Patient Cloud Open Date & Time

23 APR 2021 00:01

Patient Cloud Close Date & Time

27 APR 2021 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 APR 2021 06:11:33

Patient Cloud Open Date & Time

30 APR 2021 00:01

Patient Cloud Close Date & Time

04 MAY 2021 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

| 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"/> |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

| 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 <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"/> |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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 ☐

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2021 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

| 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"/> |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

DAY 292

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

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

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

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

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

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

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

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

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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

[Patient Cloud Close Date & Time](#)

15 JUN 2021 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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 ☐

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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 ☐

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 25 JUN 2021 00:01 |
| Patient Cloud Close Date & Time | 29 JUN 2021 23:59 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

| 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"/> |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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°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 ☐

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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°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 ☐

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 16 JUL 2021 00:01 |
| Patient Cloud Close Date & Time | 20 JUL 2021 23:59 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

| TIMEPOINT | DAY 341 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> 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"/> |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

| 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"/> |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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 ☐

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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 ☐

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 13 AUG 2021 00:01 |
| Patient Cloud Close Date & Time | 17 AUG 2021 23:59 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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 ☐

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 20 AUG 2021 00:01 |
| Patient Cloud Close Date & Time | 24 AUG 2021 23:59 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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 ☐

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 27 AUG 2021 00:01 |
| Patient Cloud Close Date & Time | 31 AUG 2021 23:59 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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 ☐

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 03 SEP 2021 00:01 |
| Patient Cloud Close Date & Time | 07 SEP 2021 23:59 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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 ☐

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 10 SEP 2021 00:01 |
| Patient Cloud Close Date & Time | 14 SEP 2021 23:59 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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 ☐

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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 ☐ Yes ☐

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

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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 ☐ Yes ☐

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

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 01 OCT 2021 00:01 |
| Patient Cloud Close Date & Time | 05 OCT 2021 23:59 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

DAY 418

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

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

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

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

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

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

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

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

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 08 OCT 2021 00:01 |
| Patient Cloud Close Date & Time | 12 OCT 2021 23:59 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

DAY 425

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

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

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

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

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

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

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

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

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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 ☐

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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

[Patient Cloud Close Date & Time](#)

26 OCT 2021 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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 ☐

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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

[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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 ☐ Yes ☐

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

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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 ☐

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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

[Patient Cloud Close Date & Time](#)

16 NOV 2021 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

| TIMEPOINT | DAY 460 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> 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"/> |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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

[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

| 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="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"/> |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 NOV 2021 00:01 |
| Patient Cloud Close Date & Time | 30 NOV 2021 23:59 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

DAY 474

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

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

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

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

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

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

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

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

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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

[Patient Cloud Close Date & Time](#)

07 DEC 2021 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

| TIMEPOINT | DAY 481 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> 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"/> |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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 ☐

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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

[Patient Cloud Close Date & Time](#)

21 DEC 2021 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

| TIMEPOINT | DAY 495 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01 |
| Patient Cloud Close Date & Time | 28 DEC 2021 23:59 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

DAY 502

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

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

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

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

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

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

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

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

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 31 DEC 2021 00:01 |
| Patient Cloud Close Date & Time | 04 JAN 2022 23:59 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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 ☐

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

DAY 516

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

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

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

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

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

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

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

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

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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 ☐

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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

[Patient Cloud Close Date & Time](#)

25 JAN 2022 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

DAY 530

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

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

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

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

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

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

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

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

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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

[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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 ☐

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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

[Patient Cloud Close Date & Time](#)

08 FEB 2022 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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 ☐

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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

[Patient Cloud Close Date & Time](#)

15 FEB 2022 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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 ☐

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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

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22 FEB 2022 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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 ☐

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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 ☐

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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

[Patient Cloud Open Date & Time](#)

04 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAR 2022 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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 ☐

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
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| Date and time of submission | |
| Patient Cloud Open Date & Time | 11 MAR 2022 00:01 |
| Patient Cloud Close Date & Time | 15 MAR 2022 23:59 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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 ☐

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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

[Patient Cloud Close Date & Time](#)

22 MAR 2022 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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 ☐

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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

[Patient Cloud Close Date & Time](#)

29 MAR 2022 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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 ☐

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

| 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"/> |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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

[Patient Cloud Close Date & Time](#)

12 APR 2022 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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

Date and time of submission

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15 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

19 APR 2022 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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 ☐ Yes ☐

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

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

| 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"/> |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

| 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="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"/> |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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

[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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 ☐

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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

[Patient Cloud Close Date & Time](#)

17 MAY 2022 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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 ☐

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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 ☐

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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

[Patient Cloud Close Date & Time](#)

31 MAY 2022 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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 ☐

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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

[Patient Cloud Close Date & Time](#)

07 JUN 2022 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

DAY 670

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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

17 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2022 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2022 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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 ☐

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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

[Patient Cloud Close Date & Time](#)

05 JUL 2022 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

| 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"/> |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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

[Patient Cloud Close Date & Time](#)

12 JUL 2022 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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 ☐

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUL 2022 00:01 |
| Patient Cloud Close Date & Time | 19 JUL 2022 23:59 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

| 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"/> |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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

[Patient Cloud Close Date & Time](#)

26 JUL 2022 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

DAY 712

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

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

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

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

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

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

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

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

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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

[Patient Cloud Close Date & Time](#)

02 AUG 2022 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

| 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"/> |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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

[Patient Cloud Close Date & Time](#)

09 AUG 2022 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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 ☐

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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

[Patient Cloud Close Date & Time](#)

16 AUG 2022 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

DAY 733

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

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

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

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

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

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

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

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

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

| TIMEPOINT | DAY 740 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> 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"/> |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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

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

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

DAY 747

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2022 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

DAY 754

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

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

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

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

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

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

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

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

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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

[Patient Cloud Close Date & Time](#)

13 SEP 2022 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

DAY 761

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2022 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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 ☐

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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

[Patient Cloud Close Date & Time](#)

27 SEP 2022 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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 ☐

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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

[Patient Cloud Close Date & Time](#)

04 OCT 2022 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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°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 ☐

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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

[Patient Cloud Close Date & Time](#)

11 OCT 2022 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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 ☐

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2022 00:01 |
| Patient Cloud Close Date & Time | 25 OCT 2022 23:59 |

US3172224

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 15:33:17

| 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 | | 05 MAR 2021 06:07:50 |

US3172224

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:11:38

Generated On: 09 Jun 2021 15:33:17

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3172224

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:11:38

Generated On: 09 Jun 2021 15:33:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172224

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:11:37

Generated On: 09 Jun 2021 15:33:17

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 15 DEC 2020

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

Comments

If Contact Not Made, please provide Comments

US3172224

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:11:37

Generated On: 09 Jun 2021 15:33:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172224

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:11:37

Generated On: 09 Jun 2021 15:33:17

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 18 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3172224

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:11:37

Generated On: 09 Jun 2021 15:33:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172224

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:11:37

Generated On: 09 Jun 2021 15:33:17

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

US3172224

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:11:37

Generated On: 09 Jun 2021 15:33:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172224

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 22 Apr 2021 16:25:33

Generated On: 09 Jun 2021 15:33:17

Was this visit performed? Yes ☐
No ☒

Visit date (dd MMM yyyy) _____

Was visit performed at the participant's home or at the clinic? Home ☐
Clinic ☐

Folder OID VISIT4

US3172224

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 22 Apr 2021 16:25:35

Generated On: 09 Jun 2021 15:33:17

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) _____

US3172224

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Apr 2021 16:25:33

Generated On: 09 Jun 2021 15:33:17

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.

US3172224

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Apr 2021 16:25:33

Generated On: 09 Jun 2021 15:33:17

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3172224

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 22 Apr 2021 16:25:33

Generated On: 09 Jun 2021 15:33:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172224

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 22 Apr 2021 16:25:33

Generated On: 09 Jun 2021 15:33:17

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 14 APR 2021

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

Comments

If Contact Not Made, please provide Comments

US3172224

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 22 Apr 2021 16:25:33

Generated On: 09 Jun 2021 15:33:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172224

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:17

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

US3172224

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:17

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3172224

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:33:17

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

US3172224

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 15:33:17

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3172224

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

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 13:11:37

Generated On: 09 Jun 2021 15:33:17

Was this visit performed? Yes ☒
No ☐

Visit date (dd MMM yyyy) 29 JAN 2021

Was visit performed at the participant's home or at the clinic? Home ☐
Clinic ☒

Folder OID UNBLND_DECIDE

US3172224

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

Form: Unblinding

Data signed: (b) (4) 22 Apr 2021 16:25:33

Generated On: 09 Jun 2021 15:33:17

| | |
|---|---|
| Date of updated informed consent (dd MMM yyyy) | 06 JAN 2021 |
| 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 (dd MMM yyyy) | 29 JAN 2021 |
| 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 |

US3172224

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 22 Apr 2021 16:25:33

Generated On: 09 Jun 2021 15:33:17

| | |
|-------------|---------------|
| Height | ND - Not Done |
| Weight | 079.7 kg |
| BMI (xxx.x) | |

US3172224

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 22 Apr 2021 16:25:33

Generated On: 09 Jun 2021 15:33:17

| | |
|-------------------------------------|--|
| Height | ND - Not Done |
| Weight | 079.7 kg |
| BMI (xxx.x) | |
| 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 MAR 2021 |
| Time of assessment (00:00-23:59) | 13:10 (24 HR) |
| Vital Signs Date and Time (derived) | 19 MAR 2021 13:10 |
| 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) | 89 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 17 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 112 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 73 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3172224

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 22 Apr 2021 16:25:33

Generated On: 09 Jun 2021 15:33:17

| | |
|-------------------------------------|--|
| Height | ND - Not Done |
| Weight | 079.7 kg |
| BMI (xxx.x) | |
| 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 MAR 2021 |
| Time of assessment (00:00-23:59) | 15:12 (24 HR) |
| Vital Signs Date and Time (derived) | 19 MAR 2021 15:12 |
| Temperature (xxx.x) | 36.6 C |
| Route of measurement | Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 61 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 16 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 123 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 80 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3172224

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

Form: Physical Examination

Data signed: (b) (4) 22 Apr 2021 16:25:33

Generated On: 09 Jun 2021 15:33:17

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 MAR 2021

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

US3172224

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

Form: Exposure

Data signed: (b) (4) 22 Apr 2021 16:25:33

Generated On: 09 Jun 2021 15:33:17

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) 19 MAR 2021

What was the treatment time? (00:00-23:59) 14:42 (24 HR)

Treatment Date and Time (derived) 19 MAR 2021 14:42

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

US3172224

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 17 Feb 2021 13:11:37

Generated On: 09 Jun 2021 15:33:17

Was the sample collected? Yes ☒
No ☐

Collection date (dd MMM yyyy) 29 JAN 2021

Collection time (00:00-23:59) 13:35 (24 HR)

Collection date and time (derived) 29 JAN 2021 13:35

US3172224

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 17 Feb 2021 13:11:37

Generated On: 09 Jun 2021 15:33:17

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

29 JAN 2021

Collection time (00:00 - 23:59)

13:36

Collection Date and Time (derived)

29 JAN 2021 13:36

US3172224

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

Form: Continuing

Data signed: (b) (4) 22 Apr 2021 16:25:33

Generated On: 09 Jun 2021 15:33:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172224

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 22 Apr 2021 16:25:33

Generated On: 09 Jun 2021 15:33:17

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 26 MAR 2021

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

Comments

If Contact Not Made, please provide Comments

US3172224

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 22 Apr 2021 16:25:33

Generated On: 09 Jun 2021 15:33:17

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

US3172224

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 22 Apr 2021 16:25:33

Generated On: 09 Jun 2021 15:33:17

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

| | |
|--------------------------|-------------|
| Visit date (dd MMM yyyy) | 13 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 | OLD29 |
|------------|-------|

US3172224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 22 Apr 2021 16:25:33

Generated On: 09 Jun 2021 15:33:17

| | |
|-------------------------------------|---|
| 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) | 13 APR 2021 |
| Time of assessment (00:00-23:59) | 13:50 (24 HR) |
| Vital Signs Date and Time (derived) | 13 APR 2021 13:50 |
| Temperature (xxx.x) | 36.7 C |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 80 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 15 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 108 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 72 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3172224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 22 Apr 2021 16:25:33

Generated On: 09 Jun 2021 15:33:17

| | |
|-------------------------------------|---|
| 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) | 13 APR 2021 |
| Time of assessment (00:00-23:59) | 15:23 (24 HR) |
| Vital Signs Date and Time (derived) | 13 APR 2021 15:23 |
| Temperature (xxx.x) | 36.8 C |
| Route of measurement | Oral <input checked="" type="checkbox"/> |
| | Axillary <input type="checkbox"/> |
| | Other <input type="checkbox"/> |
| If Other, specify | |
| Pulse (xxx) | 60 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 16 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 122 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 78 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3172224

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Apr 2021 16:25:33

Generated On: 09 Jun 2021 15:33:17

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.

US3172224

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 22 Apr 2021 16:25:33

Generated On: 09 Jun 2021 15:33:17

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) 13 APR 2021

What was the treatment time? (00:00-23:59) 14:53 (24 HR)

Treatment Date and Time (derived) 13 APR 2021 14:53

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

US3172224

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 22 Apr 2021 16:25:33

Generated On: 09 Jun 2021 15:33:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172224

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 22 Apr 2021 16:25:33

Generated On: 09 Jun 2021 15:33:17

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 21 APR 2021

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

Comments

If Contact Not Made, please provide Comments

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Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 22 Apr 2021 16:25:33

Generated On: 09 Jun 2021 15:33:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172224

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:33:17

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

Was visit performed at the participant's home or at the clinic? Home ☐
Clinic ☐

Folder OID _____

US3172224

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

| | |
|---|-----------------------------------|
| Were vital signs assessed? | Yes <input type="checkbox"/> |
| | No <input type="checkbox"/> |
| Date of assessment (<i>dd MMM yyyy</i>) | |
| Time of assessment (<i>00:00-23:59</i>) | |
| Vital Signs Date and Time (derived) | |
| Temperature (<i>xxx.x</i>) | |
| Route of measurement | Oral <input type="checkbox"/> |
| | Axillary <input type="checkbox"/> |
| | Other <input type="checkbox"/> |
| If Other, specify | |
| Pulse (<i>xxx</i>) | |
| Pulse units | |
| Respiratory Rate (<i>xxx</i>) | |
| Respiratory Rate units | |
| Systolic Blood Pressure (<i>xxx</i>) | |
| Systolic Blood Pressure units | |
| Diastolic Blood Pressure (<i>xxx</i>) | |
| Diastolic Blood Pressure units | |
| Height (derived) | |
| Weight (derived) | |

US3172224

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:33:17

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.

US3172224

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:33:17

| | |
|--|------------------------------|
| Was the sample collected? | Yes <input type="checkbox"/> |
| | No <input type="checkbox"/> |
| Collection date (<i>dd MMM yyyy</i>) | <hr/> |
| Collection time (<i>00:00-23:59</i>) | <hr/> |
| Collection date and time (derived) | <hr/> |

US3172224

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 17 Feb 2021 13:11:37

Generated On: 09 Jun 2021 15:33:17

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:17

| | |
|--|--|
| AEID | USA-US118-2021-MRNA-1273-P30 1000004 |
| Adverse event | HEMOPNEUMOTHORAX - SECONDARY TO RIB CAGE MULTIPLE FRACTURES. |
| 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) | 23 JAN 2021 |
| 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) | 27 JAN 2021 |
| 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) | 23 JAN 2021 |
| Hospital Discharge Date (dd MMM yyyy) | 27 JAN 2021 |
| 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)

Generated On: 09 Jun 2021 15:33:17

| | |
|--|---|
| 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 <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/> |
| Other action taken (check all that apply) | |
| None | False |
| Concomitant Medication | False |
| 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 | |

US3172224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:17

HEMOPNEUMOTHORAX
SECONDARY TO RIGHT RIB
CAGE MULTIPLE FRACTURES
DUE TO A MOTOR VEHICLE
ACCIDENT, REQUIRING
HOSPITALIZATION AND
THORACOTOMY. DISCHARGED
HOME, STABLE AND
RECOVERED FROM
HEMOPNEUMOTHORAX
(ACUTE / TRAUMATIC).

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

US3172224

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:17

| | |
|--|--|
| AEID | USA-US118-2021-MRNA-1273-P30 1000004 |
| Adverse event | RIGHT RIB CAGE MULTIPLE FRACTURES |
| 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) | 23 JAN 2021 |
| 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) | 1 MAR 2021 |
| End time (00:00-23:59) | |
| AE End Date and Time (derived) | |
| Severity | Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" 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) | 23 JAN 2021 |
| Hospital Discharge Date (dd MMM yyyy) | 27 JAN 2021 |
| Admitted to ICU? | Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/> |
| Number of Days in ICU | |
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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:17

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

US3172224

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:17

| | |
|--|---|
| RIGHT RIB CAGE MULTIPLE FRACTURES SECONDARY TO A MOTOR VEHICLE ACCIDENT ON 1/23/2021 REQUIRING HOSPITALIZATION DUE TO MULTIPLE TRAUMA AND HEMOPNEUMOTHORAX RESOLVED WITH THORACOSTOMY (CHEST TUBE) MULTIPLE ABRASIONS RIGHT KNEE, BOTH ELBOW, ABDOMEN, HIPS, AND FOREHEAD WITHOUT CLINICALLY SIGNIFICANCE. HE WAS DISCHARGED HOME ON 1/27/2021 ON A STABLE CONDITION WITH ORAL MEDS FOR PAIN AND SWELLING. WILL MONITOR. | |
| 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 |

US3172224

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:17

| | |
|--|--|
| AEID | |
| Adverse event | MULTIPLE SKIN ABRASIONS |
| 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) | 23 JAN 2021 |
| 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) | 03 MAR 2021 |
| 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 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 | |
| Persistent or significant disability or incapacity | False |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:17

| | |
|---|---|
| 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 | True |
| Concomitant Medication | False |
| Concomitant Procedure | False |
| Outcome | Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/> |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____ | |
| Narrative _____ | |
| 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) _____ | |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 17 Feb 2021 13:11:37

Generated On: 09 Jun 2021 15:33:17

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

Yes ☒

No ☐

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

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 22 Apr 2021 16:25:33

Generated On: 09 Jun 2021 15:33:17

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication BACK PAIN

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 22 Apr 2021 16:25:33

Generated On: 09 Jun 2021 15:33:17

| | | |
|--|--------------------------|-------------------------------------|
| | 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 1995 |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) | 19 | AUG 2020 |
| Was this medication taken for solicited event? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived) | 1 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="checkbox"/> |
| | 803 | <input type="checkbox"/> |
| | 804 | <input checked="" type="checkbox"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 22 Apr 2021 16:25:33

Generated On: 09 Jun 2021 15:33:17

Name of Medication FAMOTIDINE

Prophylaxis Yes ☐
No ☒

Indication HEARTBURN

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 22 Apr 2021 16:25:33

Generated On: 09 Jun 2021 15:33:17

| | | |
|--|--------------------------|----------------------------------|
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | UN UNK 2010 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) _____ | | |
| 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 (3)

Data signed: (b) (4) 22 Apr 2021 16:25:33

Generated On: 09 Jun 2021 15:33:17

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication HISTORICAL BACK PAIN

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 22 Apr 2021 16:25:33

Generated On: 09 Jun 2021 15:33:17

| | | |
|--|--------------------------|-------------------------------------|
| | 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 1995 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) | | 16 OCT 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"/> |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 22 Apr 2021 16:25:33

Generated On: 09 Jun 2021 15:33:17

Name of Medication OXYCODONE

Prophylaxis Yes ☐
No ☒

Indication RIGHT RIB CAGE PAIN

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

EVERY 6 HOURS

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 22 Apr 2021 16:25:33

Generated On: 09 Jun 2021 15:33:17

| | | |
|--|--------------------------|-------------------------------------|
| | 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) | | 23 JAN 2021 |
| Start date completely unknown | | False |
| Ongoing? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) 27 JAN 2021 | | |
| Was this medication taken for solicited event? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived) _____ | | |
| Interval Dosage Unit Number (derived) _____ | | |
| Interval Dosage Definition (derived) | 802 | <input type="checkbox"/> |
| | 803 | <input type="checkbox"/> |
| | 804 | <input type="checkbox"/> |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 22 Apr 2021 16:25:33

Generated On: 09 Jun 2021 15:33:17

Name of Medication TORADOL

Prophylaxis Yes ☐
No ☒

Indication RIGHT RIB CAGE PAIN

Dose per administration 15

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

EVERY 6 HOURS

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 22 Apr 2021 16:25:33

Generated On: 09 Jun 2021 15:33:17

| | | |
|--|--|-------------------------------------|
| | 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 checked="" 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) | 23 JAN 2021 | |
| Start date completely unknown | False | |
| Ongoing? | Yes <input type="checkbox"/> | |
| | No <input checked="" type="checkbox"/> | |
| If not Ongoing, End date (dd MMM yyyy) 27 JAN 2021 | | |
| Was this medication taken for solicited event? | Yes <input type="checkbox"/> | |
| | No <input checked="" type="checkbox"/> | |
| Separate Dosage Number (derived) _____ | | |
| Interval Dosage Unit Number (derived) _____ | | |
| Interval Dosage Definition (derived) | 802 | <input type="checkbox"/> |
| | 803 | <input type="checkbox"/> |
| | 804 | <input type="checkbox"/> |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 22 Apr 2021 16:25:33

Generated On: 09 Jun 2021 15:33:17

Name of Medication TOVENOX

Prophylaxis Yes ☐
No ☒

Indication RIGHT RIB CAGE PAIN

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

EVERY 12 HOURS

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 22 Apr 2021 16:25:33

Generated On: 09 Jun 2021 15:33:17

| | | |
|--|--------------------------|-------------------------------------|
| | 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) | | 23 JAN 2021 |
| Start date completely unknown | | False |
| Ongoing? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) 27 JAN 2021 | | |
| Was this medication taken for solicited event? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived) _____ | | |
| Interval Dosage Unit Number (derived) _____ | | |
| Interval Dosage Definition (derived) | 802 | <input type="checkbox"/> |
| | 803 | <input type="checkbox"/> |
| | 804 | <input type="checkbox"/> |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 22 Apr 2021 16:25:33

Generated On: 09 Jun 2021 15:33:17

Name of Medication GABAPENTIN

Prophylaxis Yes ☐
No ☒

Indication RIGHT RIB CAGE PAIN

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

EVERY 8 HOURS

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 22 Apr 2021 16:25:33

Generated On: 09 Jun 2021 15:33:17

| | | |
|--|--------------------------|-------------------------------------|
| | 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) | 23 JAN 2021 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) | | 15 MAR 2021 |
| Was this medication taken for solicited event? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived) _____ | | |
| Interval Dosage Unit Number (derived) _____ | | |
| Interval Dosage Definition (derived) | 802 | <input type="checkbox"/> |
| | 803 | <input type="checkbox"/> |
| | 804 | <input type="checkbox"/> |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 22 Apr 2021 16:25:33

Generated On: 09 Jun 2021 15:33:17

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication RIGHT RIB CAGE PAIN -
FRACTURES

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

EVERY 6 HOURS

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 22 Apr 2021 16:25:33

Generated On: 09 Jun 2021 15:33:17

| | | |
|--|--------------------------|----------------------------------|
| | Intraocular | <input type="checkbox"/> |
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify | | |
| Start date (dd MMM yyyy) | 23 JAN 2021 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | | |
| Interval Dosage Unit Number (derived) | | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input type="radio"/> |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 22 Apr 2021 16:25:33

Generated On: 09 Jun 2021 15:33:17

| | |
|--------------------------------|--|
| Name of Medication | TYLENOL |
| Prophylaxis | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Indication | RIGHT RIB CAGE PAIN - FRACTURES |
| Dose per administration | 500 |
| Dose unit | mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/> |
| If dose unit is Other, specify | |
| Frequency | once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input checked="" type="radio"/> |
| If frequency is Other, specify | |
| Route of administration | EVERY 6 HOURS Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> |

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 22 Apr 2021 16:25:33

Generated On: 09 Jun 2021 15:33:17

| | | |
|--|--------------------------|----------------------------------|
| | Intraocular | <input type="checkbox"/> |
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify | | |
| Start date (dd MMM yyyy) | 23 JAN 2021 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | | |
| Interval Dosage Unit Number (derived) | | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input type="radio"/> |

US3172224

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 17 Feb 2021 13:11:37

Generated On: 09 Jun 2021 15:33:17

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3172224

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 15:33:17

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

US3172224

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:33:17

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 ☐

US3172224

Folder: SAE USA-US118-2021-MRNA-1273-P301000004

Form: Safety Report Form

Data signed: (b) (4) 22 Apr 2021 16:25:33

Generated On: 09 Jun 2021 15:33:17

| | |
|--|--|
| SAEID | USA-US118-2021-MRNA-1273-P301000004 |
| 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 | MARK |
| Investigator's Last Name | KUTNER |
| Site Address: Street | |
| Site Address: City | |
| Site Address: State | FL |
| Site Address: Postal Code | |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 2 |

US3172224

Folder: SAE USA-US118-2021-MRNA-1273-P301000004

Form: Safety Report Form (1)

Data signed: (b) (4) 22 Apr 2021 16:25:33

Generated On: 09 Jun 2021 15:33:17

| | |
|---|--|
| SAEID | USA-US118-2021-MRNA-1273-P301000004 |
| 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 | MARK |
| Investigator's Last Name | KUTNER |
| Site Address: Street | |
| Site Address: City | |
| Site Address: State | FL |
| Site Address: Postal Code | |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 2 |
| Date of submission (Pre-filled from custom function) | 01/FEB/2021 13:13 |
| 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 |

US3172224

Folder: SAE USA-US118-2021-MRNA-1273-P301000004

Form: Safety Report Form (2)

Data signed: (b) (4) 22 Apr 2021 16:25:33

Generated On: 09 Jun 2021 15:33:17

| | |
|---|--|
| SAEID | USA-US118-2021-MRNA-1273-P301000004 |
| 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 | MARK |
| Investigator's Last Name | KUTNER |
| Site Address: Street | |
| Site Address: City | |
| Site Address: State | FL |
| Site Address: Postal Code | |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 2 |
| Date of submission (Pre-filled from custom function) | 08/APR/2021 10:29 |
| 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

US3172224 (Prod: Suncoast Research Group LLC - ERN-PPDS)

US3172224

Form: Participant Creation

Generated On: 09 Jun 2021 15:33:17

[Participant ID](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'US3172224' | RWS_ENDPOINT ENDPOINT (b) (4) (b) (4) | 19 Aug 2020 19:09:34 |

US3172224

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:33:17

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'Yes (Y)' | Mariete Rendon (b) (4) (b) (4) | 19 Aug 2020 21:08:33 |

US3172224

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered '19 AUG 2020' | RWS_ENDPOINT ENDPOINT (b) (4) (b) (4) | 19 Aug 2020 19:09:35 |

US3172224

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:33:17

[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 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| User entered 'Clinic (Clinic)' | Mariete Rendon (b) (4) | 19 Aug 2020 21:08:33 |
| | (b) (4) | |

US3172224

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:33:17

[Folder OID](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User entered 'SCRN' | System | 19 Aug 2020 21:08:33 |

US3172224

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:33:17

Date of Birth (MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered (b) (6) 1970' | RWS_ENDPOINT ENDPOINT (b) (4) (b) (4) | 19 Aug 2020 19:09:36 |

US3172224

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:33:17

[Age](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered '50' | Mariete Rendon (b) (4) (b) (4) | 19 Aug 2020 21:09:28 |

US3172224

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:33:17

[Age Units](#)

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User entered 'YEARS' | System | 19 Aug 2020 21:09:28 |

US3172224

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:33:17

[Age \(Derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User entered '50' | System | 19 Aug 2020 20:50:23 |

US3172224

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:33:17

[Sex](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'Male (M)' | Mariete Rendon (b) (4) (b) (4) | 19 Aug 2020 21:09:28 |

US3172224

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:33:17

[Ethnicity](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| User entered 'Hispanic or Latino (HISPANIC OR LATINO)' | Mariete Rendon (b) (4) | 19 Aug 2020 21:09:28 |
| | (b) (4) | |

US3172224

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:33:17

White

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| User entered 'I' | Mariete Rendon (b) (4) | 19 Aug 2020 21:09:28 |
| | (b) (4) | |

US3172224

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:33:17

[Black](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| User entered '0' | Mariete Rendon (b) (4) | 19 Aug 2020 21:09:28 |
| | (b) (4) | |

US3172224

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:33:17

[Asian](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| User entered '0' | Mariete Rendon (b) (4) | 19 Aug 2020 21:09:28 |
| | (b) (4) | |

US3172224

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:33:17

[American Indian or Alaska Native](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| User entered '0' | Mariete Rendon (b) (4) | 19 Aug 2020 21:09:28 |
| | (b) (4) | |

US3172224

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:33:17

[Native Hawaiian or other Pacific Islander](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| User entered '0' | Mariete Rendon (b) (4) | 19 Aug 2020 21:09:28 |
| | (b) (4) | |

US3172224

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:33:17

[Other](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| User entered '0' | Mariete Rendon (b) (4) | 19 Aug 2020 21:09:28 |
| | (b) (4) | |

US3172224

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:33:17

If race is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| User entered empty. | Mariete Rendon (b) (4) | 19 Aug 2020 21:09:28 |
| | (b) (4) | |

US3172224

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:33:17

Unknown

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered '0' | Mariete Rendon (b) (4) (b) (4) | 19 Aug 2020 21:09:28 |

US3172224

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:33:17

[Not reported](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| User entered '0' | Mariete Rendon (b) (4) | 19 Aug 2020 21:09:28 |
| | (b) (4) | |

US3172224

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:33:17

Date of Informed Consent (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| User entered '19 Aug 2020' | Mariete Rendon (b) (4) | 19 Aug 2020 20:50:23 |
| | (b) (4) | |

US3172224

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User entered 'Aug 2020' | System | 19 Aug 2020 20:50:23 |

US3172224

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User entered '2020' | System | 19 Aug 2020 20:50:23 |

US3172224

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:33:17

[Protocol Version](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| User entered 'Amendment 1 (1)' reason for change: | Mariete Rendon (b) (4) | 17 Sep 2020 18:59:10 |
| Data Entry Error | (b) (4) | |
| User entered 'Amendment 2 (2)' | Mariete Rendon (b) (4) | 19 Aug 2020 20:50:23 |
| | (b) (4) | |

US3172224

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'Yes (Y)' | Mariete Rendon (b) (4) (b) (4) | 19 Aug 2020 20:50:23 |

US3172224

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| User entered empty. | Mariete Rendon (b) (4) | 19 Aug 2020 20:50:23 |
| | (b) (4) | |

US3172224

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:33:17

If reason for screen fail is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| User entered empty. | Mariete Rendon (b) (4) | 19 Aug 2020 20:50:23 |
| | (b) (4) | |

US3172224

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:33:17

[Was this participant screened previously?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'No (N)' | Mariete Rendon (b) (4) (b) (4) | 19 Aug 2020 20:50:23 |

US3172224

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:33:17

[If Yes, previous participant number](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered empty. | RWS_ENDPOINT ENDPOINT (b) (4) (b) (4) | 19 Aug 2020 19:09:35 |

US3172224

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:33:17

[Enrollment Trigger](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User entered 'I' | System | 19 Aug 2020 20:50:28 |

US3172224

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'Yes (Y)' | Mariete Rendon (b) (4) (b) (4) | 19 Aug 2020 20:50:28 |

US3172224

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:33:17

[Were any significant conditions reported?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'Yes (Y)' | Mariete Rendon (b) (4) (b) (4) | 19 Aug 2020 21:13:06 |

US3172224

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:33:17

Condition

| Audit | User | Time (GMT) |
|---|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Hypermetropia, LLT: Hypermetropia - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 19 Aug 2020 22:23:11 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 19 Aug 2020 22:23:11 |
| Data point term sent to Coder | System | 19 Aug 2020 21:14:11 |
| User entered 'HYPERMETROPHIA' | Mariete Rendon (b) (4) (b) (4) | 19 Aug 2020 21:13:34 |

US3172224

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| User entered 'UN UNK 2000' | Mariete Rendon (b) (4) | 19 Aug 2020 21:13:34 |
| | (b) (4) | |

US3172224

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:33:17

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered '0' | Mariete Rendon (b) (4) (b) (4) | 19 Aug 2020 21:13:34 |

US3172224

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:33:17

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Mariete Rendon (b) (4) | 19 Aug 2020 21:13:34 |
| | (b) (4) | |

US3172224

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| User entered empty. | Mariete Rendon (b) (4) | 19 Aug 2020 21:13:34 |
| | (b) (4) | |

US3172224

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:33:17

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered '0' | Mariete Rendon (b) (4) (b) (4) | 19 Aug 2020 21:13:34 |

US3172224

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User entered 'Jan 2000' | System | 19 Aug 2020 21:13:34 |

US3172224

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User entered '2000' | System | 19 Aug 2020 21:13:34 |

US3172224

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User entered empty. | System | 19 Aug 2020 21:13:34 |

US3172224

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User entered empty. | System | 19 Aug 2020 21:13:34 |

US3172224

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:33:17

Condition

| Audit | User | Time (GMT) |
|---|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Dyspeptic signs and symptoms, PT: Dyspepsia, LLT: Heartburn - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 19 Aug 2020 21:16:10 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 19 Aug 2020 21:16:10 |
| Data point term sent to Coder | System | 19 Aug 2020 21:14:12 |
| User entered 'HEARTBURN' | Mariete Rendon (b) (4) (b) (4) | 19 Aug 2020 21:13:54 |

US3172224

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| User entered 'UN UNK 2010' | Mariete Rendon (b) (4) | 19 Aug 2020 21:13:54 |
| | (b) (4) | |

US3172224

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:33:17

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered '0' | Mariete Rendon (b) (4) (b) (4) | 19 Aug 2020 21:13:54 |

US3172224

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:33:17

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Mariete Rendon (b) (4) | 19 Aug 2020 21:13:54 |
| | (b) (4) | |

US3172224

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| User entered empty. | Mariete Rendon (b) (4) | 19 Aug 2020 21:13:54 |
| | (b) (4) | |

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Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:33:17

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| User entered '0' | Mariete Rendon (b) (4) | 19 Aug 2020 21:13:54 |
| | (b) (4) | |

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Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User entered 'Jan 2010' | System | 19 Aug 2020 21:13:54 |

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Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User entered '2010' | System | 19 Aug 2020 21:13:54 |

US3172224

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User entered empty. | System | 19 Aug 2020 21:13:54 |

US3172224

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User entered empty. | System | 19 Aug 2020 21:13:54 |

US3172224

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:33:17

Condition

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User closed query 'Per DM CLR: Please specify the location of KIDNEY STONES (e.g. right, left or both kidneys). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM). | (b) (4), (b) (6) | 21 Sep 2020 22:58:03 |
| User coded data point as SOC: Renal and urinary disorders, HLT: Urolithiasis, HLT: Renal lithiasis, PT: Nephrolithiasis, LLT: Kidney stones - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 11 Sep 2020 12:08:40 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 11 Sep 2020 12:08:40 |
| Query 'Per DM CLR: Please specify the location of KIDNEY STONES (e.g. right, left or both kidneys). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' answered with 'Data updated. No recurrence, No surgery, no liotripsy, no other treatment stone not retrieved' (Site from DM). | Mariete Rendon (b) (4) (b) (4) | 10 Sep 2020 22:41:10 |
| Data point term sent to Coder | System | 10 Sep 2020 22:40:08 |
| Coding entries removed. | Mariete Rendon (b) (4) (b) (4) | 10 Sep 2020 22:39:13 |
| User entered 'Left KIDNEY STONES' reason for change: Data Entry Error | Mariete Rendon (b) (4) (b) (4) | 10 Sep 2020 22:39:13 |
| User opened query 'Per DM CLR: Please specify the location of KIDNEY STONES (e.g. right, left or both kidneys). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM). | (b) (4), (b) (6) | 05 Sep 2020 14:35:08 |
| User coded data point as SOC: Renal and urinary disorders, HLT: Urolithiasis, HLT: Renal lithiasis, PT: Nephrolithiasis, LLT: Kidney stones - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 19 Aug 2020 21:16:10 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 19 Aug 2020 21:16:10 |

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:33:17

[Condition](#)

| Audit | User | Time (GMT) |
|-------------------------------|------------------------|----------------------|
| Data point term sent to Coder | System | 19 Aug 2020 21:15:12 |
| User entered 'KIDNEY STONES' | Mariete Rendon (b) (4) | 19 Aug 2020 21:14:19 |
| | (b) (4) | |

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Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| User entered 'UN UNK 2015' | Mariete Rendon (b) (4) | 19 Aug 2020 21:14:19 |
| | (b) (4) | |

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Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:33:17

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| User entered '0' | Mariete Rendon (b) (4) | 19 Aug 2020 21:14:19 |
| | (b) (4) | |

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Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:33:17

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| User entered 'No (N)' | Mariete Rendon (b) (4) | 19 Aug 2020 21:14:19 |
| | (b) (4) | |

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Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| User entered 'UN UNK 2015' | Mariete Rendon (b) (4) | 19 Aug 2020 21:14:19 |
| | (b) (4) | |

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Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:33:17

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| User entered '0' | Mariete Rendon (b) (4) | 19 Aug 2020 21:14:19 |
| | (b) (4) | |

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Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User entered 'Jan 2015' | System | 19 Aug 2020 21:14:19 |

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Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User entered '2015' | System | 19 Aug 2020 21:14:19 |

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Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User entered 'Jan 2015' | System | 19 Aug 2020 21:14:19 |

US3172224

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User entered '2015' | System | 19 Aug 2020 21:14:19 |

US3172224

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:33:17

Condition

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Upper limb fracture, LLT: Elbow fracture - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 19 Aug 2020 21:16:11 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 19 Aug 2020 21:16:11 |
| Data point term sent to Coder | System | 19 Aug 2020 21:15:14 |
| User entered 'RIGHT ELBOW FRACTURE' | Mariete Rendon (b) (4) (b) (4) | 19 Aug 2020 21:14:40 |

US3172224

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| User entered 'UN UNK 2015' | Mariete Rendon (b) (4) | 19 Aug 2020 21:14:40 |
| | (b) (4) | |

US3172224

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:33:17

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered '0' | Mariete Rendon (b) (4) (b) (4) | 19 Aug 2020 21:14:40 |

US3172224

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:33:17

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| User entered 'No (N)' | Mariete Rendon (b) (4) | 19 Aug 2020 21:14:40 |
| | (b) (4) | |

US3172224

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| User entered 'UN UNK 2015' | Mariete Rendon (b) (4) | 19 Aug 2020 21:14:40 |
| | (b) (4) | |

US3172224

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:33:17

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| User entered '0' | Mariete Rendon (b) (4) | 19 Aug 2020 21:14:40 |
| | (b) (4) | |

US3172224

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User entered 'Jan 2015' | System | 19 Aug 2020 21:14:40 |

US3172224

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User entered '2015' | System | 19 Aug 2020 21:14:40 |

US3172224

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User entered 'Jan 2015' | System | 19 Aug 2020 21:14:40 |

US3172224

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User entered '2015' | System | 19 Aug 2020 21:14:40 |

US3172224

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:33:17

Condition

| Audit | User | Time (GMT) |
|---|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Back pain - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 19 Aug 2020 21:16:11 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 19 Aug 2020 21:16:11 |
| Data point term sent to Coder | System | 19 Aug 2020 21:15:15 |
| User entered 'BACK PAIN' | Mariete Rendon (b) (4) (b) (4) | 19 Aug 2020 21:15:04 |

US3172224

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| User entered 'UN UNK 1995' | Mariete Rendon (b) (4) | 19 Aug 2020 21:15:04 |
| | (b) (4) | |

US3172224

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:33:17

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| User entered '0' | Mariete Rendon (b) (4) | 19 Aug 2020 21:15:04 |
| | (b) (4) | |

US3172224

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:33:17

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'Yes (Y)' | Mariete Rendon (b) (4) (b) (4) | 19 Aug 2020 21:15:04 |

US3172224

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| User entered empty. | Mariete Rendon (b) (4) | 19 Aug 2020 21:15:04 |
| | (b) (4) | |

US3172224

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:33:17

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered '0' | Mariete Rendon (b) (4) (b) (4) | 19 Aug 2020 21:15:04 |

US3172224

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User entered 'Jan 1995' | System | 19 Aug 2020 21:15:04 |

US3172224

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User entered '1995' | System | 19 Aug 2020 21:15:04 |

US3172224

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User entered empty. | System | 19 Aug 2020 21:15:04 |

US3172224

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User entered empty. | System | 19 Aug 2020 21:15:04 |

US3172224

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'Yes (Y)' | Mariete Rendon (b) (4) (b) (4) | 19 Aug 2020 21:10:05 |

US3172224

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| User entered '19 Aug 2020' | Mariete Rendon (b) (4) | 19 Aug 2020 21:10:05 |
| | (b) (4) | |

US3172224

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| User entered '13:55' | Mariete Rendon (b) (4) | 19 Aug 2020 21:10:05 |
| | (b) (4) | |

US3172224

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User entered '19 Aug 2020 13:55' | System | 19 Aug 2020 21:10:05 |

US3172224

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

Height (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered '173.3' cm | Mariete Rendon (b) (4) (b) (4) | 19 Aug 2020 21:10:05 |
| DataPoint set to visible. | System | 19 Aug 2020 20:50:28 |

US3172224

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

Weight (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered '72.2' kg | Mariete Rendon (b) (4) (b) (4) | 19 Aug 2020 21:10:05 |
| DataPoint set to visible. | System | 19 Aug 2020 20:50:28 |

US3172224

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

BMI (xxx.x)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| Amendment Manager: User entered '24.04031' | System | 17 Sep 2020 00:14:47 |
| User entered '24.0' | System | 19 Aug 2020 21:10:05 |
| DataPoint set to visible. | System | 19 Aug 2020 20:50:28 |

US3172224

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

[BMI units](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User entered 'kg/m2' | System | 19 Aug 2020 21:10:05 |
| DataPoint set to visible. | System | 19 Aug 2020 20:50:28 |

US3172224

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| User entered missing code ND - Not Done. | Mariete Rendon (b) (4) | 19 Aug 2020 21:10:05 |
| | (b) (4) | |

US3172224

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

[Route of measurement](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4), (b) (6) | 01 Sep 2020 04:53:32 |
| Query 'Data is required. Please provide.' answered with 'Not Done.' (Site from System). | Jessie Downs (b) (4) (b) (4) | 31 Aug 2020 15:33:55 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 19 Aug 2020 21:10:05 |
| User entered empty. | Mariete Rendon (b) (4) (b) (4) | 19 Aug 2020 21:10:05 |

US3172224

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered empty. | Mariete Rendon (b) (4) (b) (4) | 19 Aug 2020 21:10:05 |

US3172224

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered missing code ND - Not Done. | Mariete Rendon (b) (4) (b) (4) | 19 Aug 2020 21:10:05 |

US3172224

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User entered 'bpm' | System | 19 Aug 2020 21:10:05 |

US3172224

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered missing code ND - Not Done. | Mariete Rendon (b) (4) (b) (4) | 19 Aug 2020 21:10:05 |

US3172224

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User entered 'breaths/min' | System | 19 Aug 2020 21:10:05 |

US3172224

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered missing code ND - Not Done. | Mariete Rendon (b) (4) (b) (4) | 19 Aug 2020 21:10:05 |

US3172224

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User entered 'mmHg' | System | 19 Aug 2020 21:10:05 |

US3172224

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered missing code ND - Not Done. | Mariete Rendon (b) (4) (b) (4) | 19 Aug 2020 21:10:05 |

US3172224

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User entered 'mmHg' | System | 19 Aug 2020 21:10:05 |

US3172224

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

[Height \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| | | |

US3172224

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

Weight (derived)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| | | |

US3172224

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:33:17

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| User entered 'No (N)' reason for change: Data Entry Error | Jessie Downs (b) (4) | 28 Sep 2020 21:30:31 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Mariete Rendon (b) (4) | 19 Aug 2020 21:10:21 |
| | (b) (4) | |

US3172224

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:33:17

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| User closed query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System). | System | 28 Sep 2020 21:30:31 |
| User entered empty; reason for change Data Entry Error | Jessie Downs (b) (4) | 28 Sep 2020 21:30:31 |
| | (b) (4) | |
| User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System). | System | 16 Sep 2020 19:40:08 |
| User entered '19 Aug 2020' | Mariete Rendon (b) (4) | 19 Aug 2020 21:10:21 |
| | (b) (4) | |

US3172224

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:33:17

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 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'Yes (Y)' | Mariete Rendon (b) (4) (b) (4) | 19 Aug 2020 21:09:12 |

US3172224

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:33:17

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 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| User entered 'No (N)' | Mariete Rendon (b) (4) | 19 Aug 2020 21:09:12 |
| | (b) (4) | |

US3172224

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:33:17

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 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'No (N)' | Mariete Rendon (b) (4) (b) (4) | 19 Aug 2020 21:09:12 |

US3172224

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:33:17

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 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| User entered 'No (N)' | Mariete Rendon (b) (4) | 19 Aug 2020 21:09:12 |
| | (b) (4) | |

US3172224

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:33:17

[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 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| User entered 'No (N)' | Mariete Rendon (b) (4) | 19 Aug 2020 21:09:12 |
| | (b) (4) | |

US3172224

Folder: Screening

Form: Risk of Exposure

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[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 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'No (N)' | Mariete Rendon (b) (4) (b) (4) | 19 Aug 2020 21:09:12 |

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Folder: Screening

Form: Risk of Exposure

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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 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'No (N)' | Mariete Rendon (b) (4) (b) (4) | 19 Aug 2020 21:09:12 |

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Folder: Screening

Form: Risk of Exposure

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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 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| User entered 'No (N)' | Mariete Rendon (b) (4) | 19 Aug 2020 21:09:12 |
| | (b) (4) | |

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Folder: Screening

Form: Risk of Exposure

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[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 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'No (N)' | Mariete Rendon (b) (4) (b) (4) | 19 Aug 2020 21:09:12 |

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Folder: Screening

Form: Risk of Exposure

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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 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'No (N)' | Mariete Rendon (b) (4) (b) (4) | 19 Aug 2020 21:09:12 |

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Folder: Screening

Form: Risk of Exposure

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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 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'No (N)' | Mariete Rendon (b) (4) (b) (4) | 19 Aug 2020 21:09:12 |

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Folder: Screening

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[Other](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| User entered 'No (N)' | Mariete Rendon (b) (4) | 19 Aug 2020 21:09:12 |
| | (b) (4) | |

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Folder: Screening

Form: Risk of Exposure

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[Specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered empty. | Mariete Rendon (b) (4) (b) (4) | 19 Aug 2020 21:09:12 |

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Folder: Screening

Form: Risk of Exposure

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No Risk Identified

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| User entered '0' | Mariete Rendon (b) (4) | 19 Aug 2020 21:09:12 |
| | (b) (4) | |

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Folder: Screening

Form: Risk of Exposure

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| User entered '0' | Mariete Rendon (b) (4) | 19 Aug 2020 21:09:12 |
| | (b) (4) | |

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Folder: Screening

Form: Risk of Exposure

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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 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered '0' | Mariete Rendon (b) (4) (b) (4) | 19 Aug 2020 21:09:12 |

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Folder: Screening

Form: Risk of Exposure

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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 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| User entered '0' | Mariete Rendon (b) (4) | 19 Aug 2020 21:09:12 |
| | (b) (4) | |

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:33:17

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 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| User entered 'I' | Mariete Rendon (b) (4) | 19 Aug 2020 21:09:12 |
| | (b) (4) | |

US3172224

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered '0' | Mariete Rendon (b) (4) (b) (4) | 19 Aug 2020 21:09:12 |

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:33:17

[Other](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| User entered '0' | Mariete Rendon (b) (4) | 19 Aug 2020 21:09:12 |
| | (b) (4) | |

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Folder: Screening

Form: Risk of Exposure

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[Specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered empty. | Mariete Rendon (b) (4) (b) (4) | 19 Aug 2020 21:09:12 |

US3172224

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:33:17

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'Yes (Y)' | Mariete Rendon (b) (4) (b) (4) | 19 Aug 2020 21:10:33 |

US3172224

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:33:17

Visit date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered '19 Aug 2020' | Mariete Rendon (b) (4) (b) (4) | 19 Aug 2020 21:10:33 |

US3172224

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:33:17

Was visit performed at the participant's home or at the clinic?

| Audit | User | Time (GMT) |
|--------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| User entered 'Clinic (Clinic)' | Mariete Rendon (b) (4) | 19 Aug 2020 21:10:33 |
| | (b) (4) | |

US3172224

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:33:17

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User entered 'VISIT1' | System | 19 Aug 2020 21:10:33 |

US3172224

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered '19 AUG 2020' | RWS_ENDPOINT ENDPOINT (b) (4) (b) (4) | 19 Aug 2020 19:14:14 |

US3172224

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:33:17

What was the participant's randomization number?

| Audit | User | Time (GMT) |
|--|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System). | System | 21 Aug 2020 05:41:07 |
| Amendment Manager: Data point set to conformant. | System | 21 Aug 2020 05:41:07 |
| User opened query 'Data entered is non-conformant. Please correct.' (Site from System). | System | 19 Aug 2020 19:14:14 |
| User entered '106115' (non-conformant). | RWS_ENDPOINT ENDPOINT (b) (4) (b) (4) | 19 Aug 2020 19:14:14 |

US3172224

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|---|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered '>=18 and <65 years and not at risk (1)' | RWS_ENDPOINT ENDPOINT (b) (4) (b) (4) | 19 Aug 2020 19:14:14 |

US3172224

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:33:17

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) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'No (N)' | Mariete Rendon (b) (4) (b) (4) | 19 Aug 2020 21:16:49 |

US3172224

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:33:17

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) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'No (N)' | Mariete Rendon (b) (4) (b) (4) | 19 Aug 2020 21:16:49 |

US3172224

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'No (N)' | Mariete Rendon (b) (4) (b) (4) | 19 Aug 2020 21:16:49 |

US3172224

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:33:17

Diabetes (Type I, Type 2, or gestational)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'No (N)' | Mariete Rendon (b) (4) (b) (4) | 19 Aug 2020 21:16:49 |

US3172224

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:33:17

[Liver Disease](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'No (N)' | Mariete Rendon (b) (4) (b) (4) | 19 Aug 2020 21:16:49 |

US3172224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:33:17

Height

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered missing code ND - Not Done. | Mariete Rendon (b) (4) (b) (4) | 19 Aug 2020 21:11:04 |

US3172224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:33:17

Weight

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered missing code ND - Not Done. | Mariete Rendon (b) (4) (b) (4) | 19 Aug 2020 21:11:04 |

US3172224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:33:17

Height

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered missing code ND - Not Done. | Mariete Rendon (b) (4) (b) (4) | 19 Aug 2020 21:11:04 |

US3172224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:33:17

Weight

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered missing code ND - Not Done. | Mariete Rendon (b) (4) (b) (4) | 19 Aug 2020 21:11:04 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User accepted default value 'Pre-Dose (PREDOSE)' | Mariete Rendon (b) (4) (b) (4) | 19 Aug 2020 21:11:04 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'Yes (Y)' | Mariete Rendon (b) (4) (b) (4) | 19 Aug 2020 21:11:04 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered '19 Aug 2020' | Mariete Rendon (b) (4) (b) (4) | 19 Aug 2020 21:11:04 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered '13:55' | Mariete Rendon (b) (4) (b) (4) | 19 Aug 2020 21:11:04 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User entered '19 Aug 2020 13:55' | System | 19 Aug 2020 21:11:04 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered '37.1' C | Mariete Rendon (b) (4) (b) (4) | 19 Aug 2020 21:11:04 |

US3172224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'Oral (Oral)' | Mariete Rendon (b) (4) (b) (4) | 19 Aug 2020 21:11:04 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered empty. | Mariete Rendon (b) (4) (b) (4) | 19 Aug 2020 21:11:04 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered '84' | Mariete Rendon (b) (4) (b) (4) | 19 Aug 2020 21:11:04 |

US3172224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User entered 'bpm' | System | 19 Aug 2020 21:11:04 |

US3172224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered '16' | Mariete Rendon (b) (4) (b) (4) | 19 Aug 2020 21:11:04 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User entered 'breaths/min' | System | 19 Aug 2020 21:11:04 |

US3172224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered '114' | Mariete Rendon (b) (4) (b) (4) | 19 Aug 2020 21:11:04 |

US3172224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User entered 'mmHg' | System | 19 Aug 2020 21:11:04 |

US3172224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered '85' | Mariete Rendon (b) (4) (b) (4) | 19 Aug 2020 21:11:04 |

US3172224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User entered 'mmHg' | System | 19 Aug 2020 21:11:04 |

US3172224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:33:17

Height

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered missing code ND - Not Done. | Mariete Rendon (b) (4) (b) (4) | 19 Aug 2020 21:11:04 |

US3172224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:33:17

Weight

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered missing code ND - Not Done. | Mariete Rendon (b) (4) (b) (4) | 19 Aug 2020 21:11:04 |

US3172224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User accepted default value 'Post-Dose (POSTDOSE)' | Mariete Rendon (b) (4) (b) (4) | 19 Aug 2020 21:11:04 |

US3172224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

Were vital signs assessed?

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 20 Aug 2020 12:57:48 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 20 Aug 2020 12:57:48 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Mariete Rendon (b) (4) (b) (4) | 20 Aug 2020 12:57:48 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 19 Aug 2020 21:11:04 |
| User entered empty. | Mariete Rendon (b) (4) (b) (4) | 19 Aug 2020 21:11:04 |

US3172224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered '19 Aug 2020' reason for change: Data Entry Error | Mariete Rendon (b) (4) (b) (4) | 20 Aug 2020 12:57:48 |
| User entered empty. | Mariete Rendon (b) (4) (b) (4) | 19 Aug 2020 21:11:04 |

US3172224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|---|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| Amendment Manager: Query closed during migrationSystem process because the edit check no longer exists in target version. | | 21 Aug 2020 05:41:05 |
| User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System). | | 20 Aug 2020 12:57:48 |
| User entered '17:11' reason for change: Data Entry Error | Mariete Rendon (b) (4) (b) (4) | 20 Aug 2020 12:57:48 |
| User entered empty. | Mariete Rendon (b) (4) (b) (4) | 19 Aug 2020 21:11:04 |

US3172224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User entered '19 Aug 2020 17:11' | System | 20 Aug 2020 12:57:48 |
| User entered empty. | System | 19 Aug 2020 21:11:04 |

US3172224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered '36.6' C reason for change: Data Entry Error | Mariete Rendon (b) (4) (b) (4) | 20 Aug 2020 12:57:48 |
| User entered empty. | Mariete Rendon (b) (4) (b) (4) | 19 Aug 2020 21:11:04 |

US3172224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

[Route of measurement](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'Oral (Oral)' reason for change: Data Entry Error | Mariete Rendon (b) (4) (b) (4) | 20 Aug 2020 12:57:48 |
| User entered empty. | Mariete Rendon (b) (4) (b) (4) | 19 Aug 2020 21:11:04 |

US3172224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered empty. | Mariete Rendon (b) (4) (b) (4) | 19 Aug 2020 21:11:04 |

US3172224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered '74' reason for change: Data Entry Error | Mariete Rendon (b) (4) (b) (4) | 20 Aug 2020 12:57:48 |
| User entered empty. | Mariete Rendon (b) (4) (b) (4) | 19 Aug 2020 21:11:04 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

[Pulse units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User entered 'bpm' | System | 20 Aug 2020 12:57:48 |
| User entered empty. | System | 19 Aug 2020 21:11:04 |

US3172224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|---|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered '14' reason for change: Data Entry Error | Mariete Rendon (b) (4) (b) (4) | 20 Aug 2020 12:57:48 |
| User entered empty. | Mariete Rendon (b) (4) (b) (4) | 19 Aug 2020 21:11:04 |

US3172224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User entered 'breaths/min' | System | 20 Aug 2020 12:57:48 |
| User entered empty. | System | 19 Aug 2020 21:11:04 |

US3172224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered '119' reason for change: Data Entry Error | Mariete Rendon (b) (4) (b) (4) | 20 Aug 2020 12:57:48 |
| User entered empty. | Mariete Rendon (b) (4) (b) (4) | 19 Aug 2020 21:11:04 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User entered 'mmHg' | System | 20 Aug 2020 12:57:48 |
| User entered empty. | System | 19 Aug 2020 21:11:04 |

US3172224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered '78' reason for change: Data Entry Error | Mariete Rendon (b) (4) (b) (4) | 20 Aug 2020 12:57:48 |
| User entered empty. | Mariete Rendon (b) (4) (b) (4) | 19 Aug 2020 21:11:04 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User entered 'mmHg' | System | 20 Aug 2020 12:57:48 |
| User entered empty. | System | 19 Aug 2020 21:11:04 |

US3172224

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:33:17

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Jessie Downs (b) (4) (b) (4) | 28 Sep 2020 21:30:45 |
| User entered 'No (N)' | Mariete Rendon (b) (4) (b) (4) | 19 Aug 2020 21:11:26 |

US3172224

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:33:17

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered '19 Aug 2020' reason for change: Data Entry Error | Jessie Downs (b) (4) (b) (4) | 28 Sep 2020 21:30:45 |
| User entered empty. | Mariete Rendon (b) (4) (b) (4) | 19 Aug 2020 21:11:26 |

US3172224

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:33:17

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'Yes (Y)' | Mariete Rendon (b) (4) (b) (4) | 19 Aug 2020 20:51:16 |

US3172224

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:33:17

If No, reason not given

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered empty. | Mariete Rendon (b) (4) (b) (4) | 19 Aug 2020 20:51:16 |

US3172224

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered empty. | Mariete Rendon (b) (4) (b) (4) | 19 Aug 2020 20:51:16 |

US3172224

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:33:17

[What was the study treatment?](#)

| Audit | User | Time (GMT) |
|-------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User entered 'MRNA-1273 OR PLACEBO' | System | 19 Aug 2020 20:51:16 |

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:33:17

What was the treatment date? (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| User entered '19 Aug 2020' | Mariete Rendon (b) (4) | 19 Aug 2020 20:51:16 |
| | (b) (4) | |

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered '16:41' | Mariete Rendon (b) (4) (b) (4) | 19 Aug 2020 20:51:16 |

US3172224

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User entered '19 Aug 2020 16:41' | System | 19 Aug 2020 20:51:16 |

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|--------------------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'Right Arm (RIGHT ARM)' | Mariete Rendon (b) (4) (b) (4) | 19 Aug 2020 20:51:16 |

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User entered 'ONCE' | System | 19 Aug 2020 20:51:16 |

US3172224

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:33:17

What was the route of administration for the study treatment?

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User entered 'INTRAMUSCULAR' | System | 19 Aug 2020 20:51:16 |

US3172224

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:33:17

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'Yes (Y)' | Mariete Rendon (b) (4) (b) (4) | 19 Aug 2020 21:17:03 |

US3172224

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:33:17

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered '19 Aug 2020' | Mariete Rendon (b) (4) (b) (4) | 19 Aug 2020 21:17:03 |

US3172224

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:33:17

Collection time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered '16:06' | Mariete Rendon (b) (4) (b) (4) | 19 Aug 2020 21:17:03 |

US3172224

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User entered '19 Aug 2020 16:06' | System | 19 Aug 2020 21:17:03 |

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:33:17

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered '19 Aug 2020' | Mariete Rendon (b) (4) (b) (4) | 19 Aug 2020 21:17:16 |

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:33:17

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | Mariete Rendon (b) (4) (b) (4) | 19 Aug 2020 21:17:16 |

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:33:17

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'Yes (Y)' | Mariete Rendon (b) (4) (b) (4) | 19 Aug 2020 21:17:16 |

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:33:17

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| User entered '16:02' | Mariete Rendon (b) (4) | 19 Aug 2020 21:17:16 |
| | (b) (4) | |

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User entered '19 Aug 2020 16:02' | System | 19 Aug 2020 21:17:16 |

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:33:17

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | Mariete Rendon (b) (4) (b) (4) | 19 Aug 2020 21:17:16 |

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:33:17

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'No (N)' reason for change: Data Entry Error | Mariete Rendon (b) (4) (b) (4) | 17 Sep 2020 14:24:18 |
| User entered 'Yes (Y)' | Mariete Rendon (b) (4) (b) (4) | 19 Aug 2020 21:17:16 |

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:33:17

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered empty; reason for change Data Entry Error | Mariete Rendon (b) (4) (b) (4) | 17 Sep 2020 14:24:18 |
| User entered '16:02' | Mariete Rendon (b) (4) (b) (4) | 19 Aug 2020 21:17:16 |

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User entered empty. | System | 17 Sep 2020 14:24:18 |
| User entered '19 Aug 2020 16:02' | System | 19 Aug 2020 21:17:16 |

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:33:17

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'Yes (Y)' | Jessie Downs (b) (4) (b) (4) | 31 Aug 2020 16:22:58 |

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:33:17

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User entered 'I' | System | 31 Aug 2020 16:22:58 |

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| Data entry locked. | System | 19 Aug 2020 20:51:16 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 19 Aug 2020 20:51:16 |

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-19T17:28:43', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'c8c86128-7851-43ab-8fd0-72ccfe8f2a08' | System | 19 Aug 2020 21:29:04 |
| User entered 'Yes (Y)' | System | 19 Aug 2020 21:29:04 |

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-19T17:28:50', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'c8c86128-7851-43ab-8fd0-72ccfe8f2a08' User entered '98.3' | System | 19 Aug 2020 21:29:04 |
| | System | 19 Aug 2020 21:29:04 |

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-19T17:28:54', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'c8c86128-7851-43ab-8fd0-72ccfe8f2a08' | System | 19 Aug 2020 21:29:04 |
| User entered 'No (N)' | System | 19 Aug 2020 21:29:04 |

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-19T17:28:59', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'c8c86128-7851-43ab-8fd0-72ccfe8f2a08' | System | 19 Aug 2020 21:29:04 |
| User entered '19 Aug 2020 17:28' | System | 19 Aug 2020 21:29:04 |

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| User entered '19 Aug 2020 17:01' | System | 19 Aug 2020 20:51:16 |

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| User entered '19 Aug 2020 19:31' | System | 19 Aug 2020 20:51:16 |

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| Data entry locked. | System | 19 Aug 2020 20:51:16 |
| User entered 'Day 1, after vaccination (at home)' | System | 19 Aug 2020 20:51:16 |

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-19T20:26:51', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '3774af98-6797-45a3-b40a-fc290d313219' | System | 20 Aug 2020 00:27:14 |
| User entered 'Yes (Y)' | System | 20 Aug 2020 00:27:14 |

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-19T20:27:03', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '3774af98-6797-45a3-b40a-fc290d313219' User entered '99.0' | System | 20 Aug 2020 00:27:14 |
| | System | 20 Aug 2020 00:27:14 |

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-19T20:27:07', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '3774af98-6797-45a3-b40a-fc290d313219' User entered 'No (N)' | System | 20 Aug 2020 00:27:14 |
| | System | 20 Aug 2020 00:27:14 |

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-19T20:27:12', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '3774af98-6797-45a3-b40a-fc290d313219' User entered '19 Aug 2020 20:27' | System | 20 Aug 2020 00:27:14 |
| | System | 20 Aug 2020 00:27:14 |

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| User entered '19 Aug 2020 20:26' | System | 19 Aug 2020 20:51:16 |

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| User entered '20 Aug 2020 11:59' | System | 19 Aug 2020 20:51:16 |

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| Data entry locked. | System | 19 Aug 2020 20:51:16 |
| User entered 'Day 2' | System | 19 Aug 2020 20:51:16 |

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:33:17

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-20T14:23:42', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '1435759d-d40b-4779-9344-2f508e9c92e9' User entered 'Yes (Y)' | System | 20 Aug 2020 18:24:24 |
| | System | 20 Aug 2020 18:24:24 |

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:33:17

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-20T14:23:53', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '1435759d-d40b-4779-9344-2f508e9c92e9' User entered '98.8' | System | 20 Aug 2020 18:24:24 |
| | System | 20 Aug 2020 18:24:24 |

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-20T14:24:01', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '1435759d-d40b-4779-9344-2f508e9c92e9' User entered 'Yes (Y)' | System | 20 Aug 2020 18:24:24 |
| | System | 20 Aug 2020 18:24:24 |

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|--|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'subject denies taking any new medication' (Site from System). | Ipsita Abalokita (b) (4) (b) (4) | 08 Sep 2020 12:36:00 |
| User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). | Mariete Rendon (b) (4) (b) (4) | 02 Sep 2020 21:05:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-20T14:24:14', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '1435759d-d40b-4779-9344-2f508e9c92e9' | System | 20 Aug 2020 18:24:24 |
| User entered '1' | System | 20 Aug 2020 18:24:24 |

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:33:17

To **PREVENT** pain or fever from occurring

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-20T14:24:14', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '1435759d-d40b-4779-9344-2f508e9c92e9' User entered '0' | System | 20 Aug 2020 18:24:24 |
| | System | 20 Aug 2020 18:24:24 |

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:33:17

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-20T14:24:22', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '1435759d-d40b-4779-9344-2f508e9c92e9' User entered '20 Aug 2020 14:24' | System | 20 Aug 2020 18:24:24 |
| | System | 20 Aug 2020 18:24:24 |

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:33:17

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| User entered '20 Aug 2020 12:00' | System | 19 Aug 2020 20:51:16 |

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:33:17

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| User entered '21 Aug 2020 11:59' | System | 19 Aug 2020 20:51:16 |

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| Data entry locked. | System | 19 Aug 2020 20:51:16 |
| User entered 'Day 3' | System | 19 Aug 2020 20:51:16 |

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:33:17

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-21T14:14:41', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '3598cb7c-ab8e-45c3-94fd-e76dc63476f8' User entered 'Yes (Y)' | System | 21 Aug 2020 18:14:56 |
| | System | 21 Aug 2020 18:14:56 |

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:33:17

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-21T14:14:47', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '3598cb7c-ab8e-45c3-94fd-e76dc63476f8' User entered '98.3' | System | 21 Aug 2020 18:14:56 |
| | System | 21 Aug 2020 18:14:56 |

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-21T14:14:49', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '3598cb7c-ab8e-45c3-94fd-e76dc63476f8' User entered 'No (N)' | System | 21 Aug 2020 18:14:56 |
| | System | 21 Aug 2020 18:14:56 |

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:33:17

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-21T14:14:52', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '3598cb7c-ab8e-45c3-94fd-e76dc63476f8' User entered '21 Aug 2020 14:14' | System | 21 Aug 2020 18:14:56 |
| | System | 21 Aug 2020 18:14:56 |

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:33:17

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| User entered '21 Aug 2020 12:00' | System | 19 Aug 2020 20:51:16 |

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:33:17

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| User entered '22 Aug 2020 11:59' | System | 19 Aug 2020 20:51:16 |

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| Data entry locked. | System | 19 Aug 2020 20:51:16 |
| User entered 'Day 4' | System | 19 Aug 2020 20:51:16 |

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:33:17

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-22T14:23:28', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '955aea00-3f21-4dd1-8fc8-0f9d37b58046' User entered 'Yes (Y)' | System | 22 Aug 2020 18:23:55 |
| | System | 22 Aug 2020 18:23:55 |

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:33:17

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-22T14:23:37', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '955aea00-3f21-4dd1-8fc8-0f9d37b58046' User entered '98.8' | System | 22 Aug 2020 18:23:55 |
| | System | 22 Aug 2020 18:23:55 |

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-22T14:23:41', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '955aea00-3f21-4dd1-8fc8-0f9d37b58046' User entered 'No (N)' | System | 22 Aug 2020 18:23:55 |
| | System | 22 Aug 2020 18:23:55 |

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:33:17

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-22T14:23:53', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '955aea00-3f21-4dd1-8fc8-0f9d37b58046' User entered '22 Aug 2020 14:23' | System | 22 Aug 2020 18:23:55 |
| | System | 22 Aug 2020 18:23:55 |

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:33:17

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| User entered '22 Aug 2020 12:00' | System | 19 Aug 2020 20:51:16 |

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:33:17

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| User entered '23 Aug 2020 11:59' | System | 19 Aug 2020 20:51:16 |

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| Data entry locked. | System | 19 Aug 2020 20:51:16 |
| User entered 'Day 5' | System | 19 Aug 2020 20:51:16 |

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:33:17

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-23T15:40:30', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '3e65f33d-2767-4cd2-b876-db9021b9000e' User entered 'Yes (Y)' | System | 23 Aug 2020 19:40:48 |
| | System | 23 Aug 2020 19:40:48 |

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:33:17

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-23T15:40:37', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '3e65f33d-2767-4cd2-b876-db9021b9000e' User entered '97.9' | System | 23 Aug 2020 19:40:48 |
| | System | 23 Aug 2020 19:40:48 |

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-23T15:40:40', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '3e65f33d-2767-4cd2-b876-db9021b9000e' User entered 'No (N)' | System | 23 Aug 2020 19:40:48 |
| | System | 23 Aug 2020 19:40:48 |

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:33:17

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-23T15:40:43', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '3e65f33d-2767-4cd2-b876-db9021b9000e' User entered '23 Aug 2020 15:40' | System | 23 Aug 2020 19:40:48 |
| | System | 23 Aug 2020 19:40:48 |

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:33:17

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| User entered '23 Aug 2020 12:00' | System | 19 Aug 2020 20:51:16 |

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:33:17

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| User entered '24 Aug 2020 11:59' | System | 19 Aug 2020 20:51:16 |

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| Data entry locked. | System | 19 Aug 2020 20:51:16 |
| User entered 'Day 6' | System | 19 Aug 2020 20:51:16 |

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:33:17

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-24T14:47:24', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '78939004-b03b-4e7d-bf9a-8e812bc99208' User entered 'Yes (Y)' | System | 24 Aug 2020 18:47:41 |
| | System | 24 Aug 2020 18:47:41 |

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:33:17

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-24T14:47:29', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '78939004-b03b-4e7d-bf9a-8e812bc99208' User entered '98.8' | System | 24 Aug 2020 18:47:41 |
| | System | 24 Aug 2020 18:47:41 |

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-24T14:47:32', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '78939004-b03b-4e7d-bf9a-8e812bc99208' | System | 24 Aug 2020 18:47:41 |
| User entered 'No (N)' | System | 24 Aug 2020 18:47:41 |

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:33:17

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-24T14:47:34', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '78939004-b03b-4e7d-bf9a-8e812bc99208' User entered '24 Aug 2020 14:47' | System | 24 Aug 2020 18:47:41 |
| | System | 24 Aug 2020 18:47:41 |

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:33:17

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| User entered '24 Aug 2020 12:00' | System | 19 Aug 2020 20:51:16 |

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:33:17

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| User entered '25 Aug 2020 11:59' | System | 19 Aug 2020 20:51:16 |

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| Data entry locked. | System | 19 Aug 2020 20:51:16 |
| User entered 'Day 7' | System | 19 Aug 2020 20:51:16 |

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:33:17

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-25T18:06:06', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '7f261fd2-3b19-4e71-bfbe-46cfa897c10' | System | 25 Aug 2020 22:06:26 |
| User entered 'Yes (Y)' | System | 25 Aug 2020 22:06:26 |

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:33:17

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-25T18:06:18', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '7f261fd2-3b19-4e71-bfbe-46cfa897c10' User entered '98.4' | System | 25 Aug 2020 22:06:26 |
| | System | 25 Aug 2020 22:06:26 |

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-25T18:06:20', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '7f261fd2-3b19-4e71-bfbe-46cfa897c10' | System | 25 Aug 2020 22:06:26 |
| User entered 'No (N)' | System | 25 Aug 2020 22:06:26 |

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:33:17

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-25T18:06:23', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '7f261fd2-3b19-4e71-bfbe-46cfa897c10' User entered '25 Aug 2020 18:06' | System | 25 Aug 2020 22:06:26 |
| | System | 25 Aug 2020 22:06:26 |

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:33:17

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| User entered '25 Aug 2020 12:00' | System | 19 Aug 2020 20:51:16 |

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:33:17

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| User entered '26 Aug 2020 11:59' | System | 19 Aug 2020 20:51:16 |

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| Data entry locked. | System | 19 Aug 2020 20:51:16 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 19 Aug 2020 20:51:16 |

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-19T17:29:06', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '59f2e3eb-ffa5-4327-ac52-04ca036ef57a' User entered 'None (1)' | System | 19 Aug 2020 21:29:37 |
| | System | 19 Aug 2020 21:29:37 |

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-19T17:29:09', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '59f2e3eb-ffa5-4327-ac52-04ca036ef57a' User entered 'No (N)' | System | 19 Aug 2020 21:29:37 |
| | System | 19 Aug 2020 21:29:37 |

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-19T17:29:11', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '59f2e3eb-ffa5-4327-ac52-04ca036ef57a' User entered 'No (N)' | System | 19 Aug 2020 21:29:37 |
| | System | 19 Aug 2020 21:29:37 |

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-19T17:29:30', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '59f2e3eb-ffa5-4327-ac52-04ca036ef57a' User entered 'None (1)' | System | 19 Aug 2020 21:29:37 |
| | System | 19 Aug 2020 21:29:37 |

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-19T17:29:35', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '59f2e3eb-ffa5-4327-ac52-04ca036ef57a' User entered '19 Aug 2020 17:29' | System | 19 Aug 2020 21:29:37 |
| | System | 19 Aug 2020 21:29:37 |

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| User entered '19 Aug 2020 17:01' | System | 19 Aug 2020 20:51:16 |

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| User entered '19 Aug 2020 19:31' | System | 19 Aug 2020 20:51:16 |

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| Data entry locked. | System | 19 Aug 2020 20:51:16 |
| User entered 'Day 1, after vaccination (at home)' | System | 19 Aug 2020 20:51:16 |

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-19T20:27:51', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '258b9e05-1fd0-45b6-badf-3326d6dc75eb' User entered 'None (1)' | System | 20 Aug 2020 00:28:07 |
| | System | 20 Aug 2020 00:28:07 |

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-19T20:27:54', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '258b9e05-1fd0-45b6-badf-3326d6dc75eb' User entered 'No (N)' | System | 20 Aug 2020 00:28:07 |
| | System | 20 Aug 2020 00:28:07 |

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-19T20:27:56', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '258b9e05-1fd0-45b6-badf-3326d6dc75eb' User entered 'No (N)' | System | 20 Aug 2020 00:28:07 |
| | System | 20 Aug 2020 00:28:07 |

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-19T20:28:02', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '258b9e05-1fd0-45b6-badf-3326d6dc75eb' User entered 'None (1)' | System | 20 Aug 2020 00:28:07 |
| | System | 20 Aug 2020 00:28:07 |

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-19T20:28:04', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '258b9e05-1fd0-45b6-badf-3326d6dc75eb' User entered '19 Aug 2020 20:28' | System | 20 Aug 2020 00:28:07 |
| | System | 20 Aug 2020 00:28:07 |

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| User entered '19 Aug 2020 20:26' | System | 19 Aug 2020 20:51:16 |

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| User entered '20 Aug 2020 11:59' | System | 19 Aug 2020 20:51:16 |

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| Data entry locked. | System | 19 Aug 2020 20:51:16 |
| User entered 'Day 2' | System | 19 Aug 2020 20:51:16 |

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:33:17

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-20T14:24:27', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'f3722669-a959-41d2-b2d0-d421465141d1' User entered 'None (1)' | System | 20 Aug 2020 18:24:43 |
| | System | 20 Aug 2020 18:24:43 |

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:33:17

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-20T14:24:30', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'f3722669-a959-41d2-b2d0-d421465141d1' User entered 'No (N)' | System | 20 Aug 2020 18:24:43 |
| | System | 20 Aug 2020 18:24:43 |

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-20T14:24:33', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'f3722669-a959-41d2-b2d0-d421465141d1' User entered 'No (N)' | System | 20 Aug 2020 18:24:43 |
| | System | 20 Aug 2020 18:24:43 |

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:33:17

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-20T14:24:37', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'f3722669-a959-41d2-b2d0-d421465141d1' User entered 'None (1)' | System | 20 Aug 2020 18:24:43 |
| | System | 20 Aug 2020 18:24:43 |

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:33:17

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-20T14:24:40', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'f3722669-a959-41d2-b2d0-d421465141d1' User entered '20 Aug 2020 14:24' | System | 20 Aug 2020 18:24:43 |
| | System | 20 Aug 2020 18:24:43 |

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:33:17

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| User entered '20 Aug 2020 12:00' | System | 19 Aug 2020 20:51:16 |

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:33:17

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| User entered '21 Aug 2020 11:59' | System | 19 Aug 2020 20:51:16 |

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| Data entry locked. | System | 19 Aug 2020 20:51:16 |
| User entered 'Day 3' | System | 19 Aug 2020 20:51:16 |

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:33:17

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-21T14:14:19', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '074fad62-257e-45a6-8204-c1a19eeaf167' | System | 21 Aug 2020 18:14:36 |
| User entered 'None (1)' | System | 21 Aug 2020 18:14:36 |

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:33:17

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-21T14:14:22', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '074fad62-257e-45a6-8204-c1a19eeaf167' | System | 21 Aug 2020 18:14:36 |
| User entered 'No (N)' | System | 21 Aug 2020 18:14:36 |

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-21T14:14:26', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '074fad62-257e-45a6-8204-c1a19eeaf167' | System | 21 Aug 2020 18:14:36 |
| User entered 'No (N)' | System | 21 Aug 2020 18:14:36 |

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:33:17

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-21T14:14:29', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '074fad62-257e-45a6-8204-c1a19eeaf167' | System | 21 Aug 2020 18:14:36 |
| User entered 'None (1)' | System | 21 Aug 2020 18:14:36 |

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:33:17

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-21T14:14:35', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '074fad62-257e-45a6-8204-c1a19eeaf167' | System | 21 Aug 2020 18:14:36 |
| User entered '21 Aug 2020 14:14' | System | 21 Aug 2020 18:14:36 |

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:33:17

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| User entered '21 Aug 2020 12:00' | System | 19 Aug 2020 20:51:16 |

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:33:17

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| User entered '22 Aug 2020 11:59' | System | 19 Aug 2020 20:51:16 |

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| Data entry locked. | System | 19 Aug 2020 20:51:16 |
| User entered 'Day 4' | System | 19 Aug 2020 20:51:16 |

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:33:17

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-22T14:23:58', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'de2ddd4c-e8cf-47bb-98ef-12cb88f2729e' User entered 'None (1)' | System | 22 Aug 2020 18:24:18 |
| | System | 22 Aug 2020 18:24:18 |

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:33:17

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-22T14:24:04', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'de2ddd4c-e8cf-47bb-98ef-12cb88f2729e' User entered 'No (N)' | System | 22 Aug 2020 18:24:18 |
| | System | 22 Aug 2020 18:24:18 |

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-22T14:24:07', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'de2ddd4c-e8cf-47bb-98ef-12cb88f2729e' User entered 'No (N)' | System | 22 Aug 2020 18:24:18 |
| | System | 22 Aug 2020 18:24:18 |

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:33:17

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-22T14:24:11', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'de2ddd4c-e8cf-47bb-98ef-12cb88f2729e' User entered 'None (1)' | System | 22 Aug 2020 18:24:18 |
| | System | 22 Aug 2020 18:24:18 |

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:33:17

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-22T14:24:14', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'de2ddd4c-e8cf-47bb-98ef-12cb88f2729e' User entered '22 Aug 2020 14:24' | System | 22 Aug 2020 18:24:18 |
| | System | 22 Aug 2020 18:24:18 |

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:33:17

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| User entered '22 Aug 2020 12:00' | System | 19 Aug 2020 20:51:16 |

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:33:17

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| User entered '23 Aug 2020 11:59' | System | 19 Aug 2020 20:51:16 |

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| Data entry locked. | System | 19 Aug 2020 20:51:16 |
| User entered 'Day 5' | System | 19 Aug 2020 20:51:16 |

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:33:17

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-23T15:40:48', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'f0fa3674-6d82-41d9-bd3a-a6ba815173ed' User entered 'None (1)' | System | 23 Aug 2020 19:41:04 |
| | System | 23 Aug 2020 19:41:04 |

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:33:17

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-23T15:40:50', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'f0fa3674-6d82-41d9-bd3a-a6ba815173ed' User entered 'No (N)' | System | 23 Aug 2020 19:41:04 |
| | System | 23 Aug 2020 19:41:04 |

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-23T15:40:53', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'f0fa3674-6d82-41d9-bd3a-a6ba815173ed' User entered 'No (N)' | System | 23 Aug 2020 19:41:04 |
| | System | 23 Aug 2020 19:41:04 |

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:33:17

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-23T15:40:55', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'f0fa3674-6d82-41d9-bd3a-a6ba815173ed' User entered 'None (1)' | System | 23 Aug 2020 19:41:04 |
| | System | 23 Aug 2020 19:41:04 |

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:33:17

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-23T15:41:01', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'f0fa3674-6d82-41d9-bd3a-a6ba815173ed' User entered '23 Aug 2020 15:41' | System | 23 Aug 2020 19:41:04 |
| | System | 23 Aug 2020 19:41:04 |

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:33:17

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| User entered '23 Aug 2020 12:00' | System | 19 Aug 2020 20:51:16 |

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:33:17

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| User entered '24 Aug 2020 11:59' | System | 19 Aug 2020 20:51:16 |

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| Data entry locked. | System | 19 Aug 2020 20:51:16 |
| User entered 'Day 6' | System | 19 Aug 2020 20:51:16 |

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:33:17

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-24T14:47:38', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '62028bfa-c9a3-43f9-8fd3-b5aaf5e453d7' | System | 24 Aug 2020 18:47:49 |
| User entered 'None (1)' | System | 24 Aug 2020 18:47:49 |

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:33:17

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-24T14:47:40', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '62028bfa-c9a3-43f9-8fd3-b5aaf5e453d7' User entered 'No (N)' | System | 24 Aug 2020 18:47:49 |
| | System | 24 Aug 2020 18:47:49 |

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-24T14:47:42', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '62028bfa-c9a3-43f9-8fd3-b5aaf5e453d7' User entered 'No (N)' | System | 24 Aug 2020 18:47:49 |
| | System | 24 Aug 2020 18:47:49 |

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:33:17

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-24T14:47:44', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '62028bfa-c9a3-43f9-8fd3-b5aaf5e453d7' User entered 'None (1)' | System | 24 Aug 2020 18:47:49 |
| | System | 24 Aug 2020 18:47:49 |

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:33:17

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-24T14:47:46', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '62028bfa-c9a3-43f9-8fd3-b5aaf5e453d7' User entered '24 Aug 2020 14:47' | System | 24 Aug 2020 18:47:49 |
| | System | 24 Aug 2020 18:47:49 |

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:33:17

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| User entered '24 Aug 2020 12:00' | System | 19 Aug 2020 20:51:16 |

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:33:17

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| User entered '25 Aug 2020 11:59' | System | 19 Aug 2020 20:51:16 |

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| Data entry locked. | System | 19 Aug 2020 20:51:16 |
| User entered 'Day 7' | System | 19 Aug 2020 20:51:16 |

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:33:17

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-25T18:06:27', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '9eb98b17-e0e2-442c-9d17-5eba50726333' User entered 'None (1)' | System | 25 Aug 2020 22:06:38 |
| | System | 25 Aug 2020 22:06:38 |

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:33:17

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-25T18:06:29', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '9eb98b17-e0e2-442c-9d17-5eba50726333' User entered 'No (N)' | System | 25 Aug 2020 22:06:38 |
| | System | 25 Aug 2020 22:06:38 |

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-25T18:06:31', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '9eb98b17-e0e2-442c-9d17-5eba50726333' User entered 'No (N)' | System | 25 Aug 2020 22:06:38 |
| | System | 25 Aug 2020 22:06:38 |

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:33:17

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-25T18:06:33', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '9eb98b17-e0e2-442c-9d17-5eba50726333' User entered 'None (1)' | System | 25 Aug 2020 22:06:38 |
| | System | 25 Aug 2020 22:06:38 |

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:33:17

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-25T18:06:36', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '9eb98b17-e0e2-442c-9d17-5eba50726333' User entered '25 Aug 2020 18:06' | System | 25 Aug 2020 22:06:38 |
| | System | 25 Aug 2020 22:06:38 |

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:33:17

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| User entered '25 Aug 2020 12:00' | System | 19 Aug 2020 20:51:16 |

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:33:17

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| User entered '26 Aug 2020 11:59' | System | 19 Aug 2020 20:51:16 |

US3172224

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| Data entry locked. | System | 19 Aug 2020 20:51:16 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 19 Aug 2020 20:51:16 |

US3172224

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-19T17:29:42', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'ad16fdf1-dcfa-4159-b57b-ea53c099b245' | System | 19 Aug 2020 21:29:59 |
| User entered 'None (0)' | System | 19 Aug 2020 21:29:59 |

US3172224

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-19T17:29:44', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'ad16fdf1-dcfa-4159-b57b-ea53c099b245' | System | 19 Aug 2020 21:29:59 |
| User entered 'None (0)' | System | 19 Aug 2020 21:29:59 |

US3172224

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-19T17:29:46', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'ad16fdf1-dcfa-4159-b57b-ea53c099b245' | System | 19 Aug 2020 21:29:59 |
| User entered 'None (0)' | System | 19 Aug 2020 21:29:59 |

US3172224

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-19T17:29:48', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'ad16fdf1-dcfa-4159-b57b-ea53c099b245' User entered 'None (0)' | System | 19 Aug 2020 21:29:59 |
| | System | 19 Aug 2020 21:29:59 |

US3172224

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-19T17:29:50', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'ad16fdf1-dcfa-4159-b57b-ea53c099b245' | System | 19 Aug 2020 21:29:59 |
| User entered 'None (0)' | System | 19 Aug 2020 21:29:59 |

US3172224

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-19T17:29:51', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'ad16fdf1-dcfa-4159-b57b-ea53c099b245' | System | 19 Aug 2020 21:29:59 |
| User entered 'None (0)' | System | 19 Aug 2020 21:29:59 |

US3172224

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-19T17:29:53', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'ad16fdf1-dcfa-4159-b57b-ea53c099b245' | System | 19 Aug 2020 21:29:59 |
| User entered 'No (N)' | System | 19 Aug 2020 21:29:59 |

US3172224

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-19T17:29:56', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'ad16fdf1-dcfa-4159-b57b-ea53c099b245' | System | 19 Aug 2020 21:29:59 |
| User entered '19 Aug 2020 17:29' | System | 19 Aug 2020 21:29:59 |

US3172224

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| User entered '19 Aug 2020 17:01' | System | 19 Aug 2020 20:51:16 |

US3172224

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| User entered '19 Aug 2020 19:31' | System | 19 Aug 2020 20:51:16 |

US3172224

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| Data entry locked. | System | 19 Aug 2020 20:51:16 |
| User entered 'Day 1, after vaccination (at home)' | System | 19 Aug 2020 20:51:16 |

US3172224

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-19T20:27:20', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '1e60d67c-2eb0-4430-84eb-07908f4de335' User entered 'None (0)' | System | 20 Aug 2020 00:27:48 |
| | System | 20 Aug 2020 00:27:48 |

US3172224

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-19T20:27:24', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '1e60d67c-2eb0-4430-84eb-07908f4de335' User entered 'None (0)' | System | 20 Aug 2020 00:27:48 |
| | System | 20 Aug 2020 00:27:48 |

US3172224

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-19T20:27:27', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '1e60d67c-2eb0-4430-84eb-07908f4de335' User entered 'None (0)' | System | 20 Aug 2020 00:27:48 |
| | System | 20 Aug 2020 00:27:48 |

US3172224

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-19T20:27:29', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '1e60d67c-2eb0-4430-84eb-07908f4de335' User entered 'None (0)' | System | 20 Aug 2020 00:27:48 |
| | System | 20 Aug 2020 00:27:48 |

US3172224

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-19T20:27:33', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '1e60d67c-2eb0-4430-84eb-07908f4de335' User entered 'None (0)' | System | 20 Aug 2020 00:27:48 |
| | System | 20 Aug 2020 00:27:48 |

US3172224

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-19T20:27:37', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '1e60d67c-2eb0-4430-84eb-07908f4de335' User entered 'None (0)' | System | 20 Aug 2020 00:27:48 |
| | System | 20 Aug 2020 00:27:48 |

US3172224

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-19T20:27:42', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '1e60d67c-2eb0-4430-84eb-07908f4de335' | System | 20 Aug 2020 00:27:48 |
| User entered 'No (N)' | System | 20 Aug 2020 00:27:48 |

US3172224

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-19T20:27:45', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '1e60d67c-2eb0-4430-84eb-07908f4de335' User entered '19 Aug 2020 20:27' | System | 20 Aug 2020 00:27:48 |
| | System | 20 Aug 2020 00:27:48 |

US3172224

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| User entered '19 Aug 2020 20:26' | System | 19 Aug 2020 20:51:16 |

US3172224

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| User entered '20 Aug 2020 11:59' | System | 19 Aug 2020 20:51:16 |

US3172224

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| Data entry locked. | System | 19 Aug 2020 20:51:16 |
| User entered 'Day 2' | System | 19 Aug 2020 20:51:16 |

US3172224

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:33:17

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-20T14:24:47', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '89f8e7a5-8180-4a91-9298-5d8154c29342' User entered 'None (0)' | System | 20 Aug 2020 18:25:05 |
| | System | 20 Aug 2020 18:25:05 |

US3172224

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:33:17

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-20T14:24:48', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '89f8e7a5-8180-4a91-9298-5d8154c29342' User entered 'None (0)' | System | 20 Aug 2020 18:25:05 |
| | System | 20 Aug 2020 18:25:05 |

US3172224

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:33:17

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-20T14:24:50', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '89f8e7a5-8180-4a91-9298-5d8154c29342' User entered 'None (0)' | System | 20 Aug 2020 18:25:05 |
| | System | 20 Aug 2020 18:25:05 |

US3172224

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:33:17

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-20T14:24:52', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '89f8e7a5-8180-4a91-9298-5d8154c29342' User entered 'None (0)' | System | 20 Aug 2020 18:25:05 |
| | System | 20 Aug 2020 18:25:05 |

US3172224

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:33:17

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-20T14:24:54', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '89f8e7a5-8180-4a91-9298-5d8154c29342' User entered 'None (0)' | System | 20 Aug 2020 18:25:05 |
| | System | 20 Aug 2020 18:25:05 |

US3172224

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:33:17

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-20T14:24:56', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '89f8e7a5-8180-4a91-9298-5d8154c29342' User entered 'None (0)' | System | 20 Aug 2020 18:25:05 |
| | System | 20 Aug 2020 18:25:05 |

US3172224

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-20T14:24:59', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '89f8e7a5-8180-4a91-9298-5d8154c29342' | System | 20 Aug 2020 18:25:05 |
| User entered 'No (N)' | System | 20 Aug 2020 18:25:05 |

US3172224

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:33:17

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-20T14:25:02', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '89f8e7a5-8180-4a91-9298-5d8154c29342' | System | 20 Aug 2020 18:25:05 |
| User entered '20 Aug 2020 14:25' | System | 20 Aug 2020 18:25:05 |

US3172224

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:33:17

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| User entered '20 Aug 2020 12:00' | System | 19 Aug 2020 20:51:16 |

US3172224

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:33:17

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| User entered '21 Aug 2020 11:59' | System | 19 Aug 2020 20:51:16 |

US3172224

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| Data entry locked. | System | 19 Aug 2020 20:51:16 |
| User entered 'Day 3' | System | 19 Aug 2020 20:51:16 |

US3172224

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:33:17

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-21T14:14:56', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '93bf3766-7293-4c5c-92c6-5468804f80cc' User entered 'None (0)' | System | 21 Aug 2020 18:15:14 |
| | System | 21 Aug 2020 18:15:14 |

US3172224

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:33:17

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-21T14:14:58', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '93bf3766-7293-4c5c-92c6-5468804f80cc' User entered 'None (0)' | System | 21 Aug 2020 18:15:14 |
| | System | 21 Aug 2020 18:15:14 |

US3172224

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:33:17

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-21T14:15:00', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '93bf3766-7293-4c5c-92c6-5468804f80cc' User entered 'None (0)' | System | 21 Aug 2020 18:15:14 |
| | System | 21 Aug 2020 18:15:14 |

US3172224

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:33:17

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-21T14:15:02', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '93bf3766-7293-4c5c-92c6-5468804f80cc' User entered 'None (0)' | System | 21 Aug 2020 18:15:14 |
| | System | 21 Aug 2020 18:15:14 |

US3172224

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:33:17

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-21T14:15:04', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '93bf3766-7293-4c5c-92c6-5468804f80cc' User entered 'None (0)' | System | 21 Aug 2020 18:15:14 |
| | System | 21 Aug 2020 18:15:14 |

US3172224

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:33:17

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-21T14:15:05', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '93bf3766-7293-4c5c-92c6-5468804f80cc' User entered 'None (0)' | System | 21 Aug 2020 18:15:14 |
| | System | 21 Aug 2020 18:15:14 |

US3172224

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-21T14:15:08', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '93bf3766-7293-4c5c-92c6-5468804f80cc' User entered 'No (N)' | System | 21 Aug 2020 18:15:14 |
| | System | 21 Aug 2020 18:15:14 |

US3172224

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:33:17

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-21T14:15:10', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '93bf3766-7293-4c5c-92c6-5468804f80cc' User entered '21 Aug 2020 14:15' | System | 21 Aug 2020 18:15:14 |
| | System | 21 Aug 2020 18:15:14 |

US3172224

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:33:17

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| User entered '21 Aug 2020 12:00' | System | 19 Aug 2020 20:51:16 |

US3172224

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:33:17

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| User entered '22 Aug 2020 11:59' | System | 19 Aug 2020 20:51:16 |

US3172224

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| Data entry locked. | System | 19 Aug 2020 20:51:16 |
| User entered 'Day 4' | System | 19 Aug 2020 20:51:16 |

US3172224

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:33:17

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-22T14:24:18', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'b47807be-62ef-49d6-8908-010e51a85a63' User entered 'None (0)' | System | 22 Aug 2020 18:24:40 |
| | System | 22 Aug 2020 18:24:40 |

US3172224

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:33:17

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-22T14:24:20', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'b47807be-62ef-49d6-8908-010e51a85a63' User entered 'None (0)' | System | 22 Aug 2020 18:24:40 |
| | System | 22 Aug 2020 18:24:40 |

US3172224

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:33:17

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-22T14:24:22', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'b47807be-62ef-49d6-8908-010e51a85a63' User entered 'None (0)' | System | 22 Aug 2020 18:24:40 |
| | System | 22 Aug 2020 18:24:40 |

US3172224

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:33:17

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-22T14:24:24', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'b47807be-62ef-49d6-8908-010e51a85a63' User entered 'None (0)' | System | 22 Aug 2020 18:24:40 |
| | System | 22 Aug 2020 18:24:40 |

US3172224

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:33:17

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-22T14:24:27', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'b47807be-62ef-49d6-8908-010e51a85a63' User entered 'None (0)' | System | 22 Aug 2020 18:24:40 |
| | System | 22 Aug 2020 18:24:40 |

US3172224

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:33:17

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-22T14:24:29', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'b47807be-62ef-49d6-8908-010e51a85a63' User entered 'None (0)' | System | 22 Aug 2020 18:24:40 |
| | System | 22 Aug 2020 18:24:40 |

US3172224

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-22T14:24:34', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'b47807be-62ef-49d6-8908-010e51a85a63' | System | 22 Aug 2020 18:24:40 |
| User entered 'No (N)' | System | 22 Aug 2020 18:24:40 |

US3172224

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:33:17

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-22T14:24:37', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'b47807be-62ef-49d6-8908-010e51a85a63' User entered '22 Aug 2020 14:24' | System | 22 Aug 2020 18:24:40 |
| | System | 22 Aug 2020 18:24:40 |

US3172224

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:33:17

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| User entered '22 Aug 2020 12:00' | System | 19 Aug 2020 20:51:16 |

US3172224

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:33:17

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| User entered '23 Aug 2020 11:59' | System | 19 Aug 2020 20:51:16 |

US3172224

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| Data entry locked. | System | 19 Aug 2020 20:51:16 |
| User entered 'Day 5' | System | 19 Aug 2020 20:51:16 |

US3172224

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:33:17

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-23T15:41:07', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'dc536325-3623-40e7-80b6-4ddf277e26f4' User entered 'None (0)' | System | 23 Aug 2020 19:41:25 |
| | System | 23 Aug 2020 19:41:25 |

US3172224

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:33:17

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-23T15:41:09', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'dc536325-3623-40e7-80b6-4ddf277e26f4' User entered 'None (0)' | System | 23 Aug 2020 19:41:25 |
| | System | 23 Aug 2020 19:41:25 |

US3172224

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:33:17

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-23T15:41:11', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'dc536325-3623-40e7-80b6-4ddf277e26f4' User entered 'None (0)' | System | 23 Aug 2020 19:41:25 |
| | System | 23 Aug 2020 19:41:25 |

US3172224

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:33:17

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-23T15:41:13', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'dc536325-3623-40e7-80b6-4ddf277e26f4' User entered 'None (0)' | System | 23 Aug 2020 19:41:25 |
| | System | 23 Aug 2020 19:41:25 |

US3172224

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:33:17

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-23T15:41:15', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'dc536325-3623-40e7-80b6-4ddf277e26f4' User entered 'None (0)' | System | 23 Aug 2020 19:41:25 |
| | System | 23 Aug 2020 19:41:25 |

US3172224

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:33:17

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-23T15:41:17', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'dc536325-3623-40e7-80b6-4ddf277e26f4' User entered 'None (0)' | System | 23 Aug 2020 19:41:25 |
| | System | 23 Aug 2020 19:41:25 |

US3172224

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-23T15:41:19', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'dc536325-3623-40e7-80b6-4ddf277e26f4' User entered 'No (N)' | System | 23 Aug 2020 19:41:25 |
| | System | 23 Aug 2020 19:41:25 |

US3172224

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:33:17

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-23T15:41:21', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'dc536325-3623-40e7-80b6-4ddf277e26f4' User entered '23 Aug 2020 15:41' | System | 23 Aug 2020 19:41:25 |
| | System | 23 Aug 2020 19:41:25 |

US3172224

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:33:17

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| User entered '23 Aug 2020 12:00' | System | 19 Aug 2020 20:51:16 |

US3172224

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:33:17

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| User entered '24 Aug 2020 11:59' | System | 19 Aug 2020 20:51:16 |

US3172224

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| Data entry locked. | System | 19 Aug 2020 20:51:16 |
| User entered 'Day 6' | System | 19 Aug 2020 20:51:16 |

US3172224

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:33:17

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-24T14:47:49', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'c4dbd9c4-ea29-466e-b6d1-a9b62d7c081e' User entered 'None (0)' | System | 24 Aug 2020 18:48:05 |
| | System | 24 Aug 2020 18:48:05 |

US3172224

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:33:17

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-24T14:47:51', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'c4dbd9c4-ea29-466e-b6d1-a9b62d7c081e' User entered 'None (0)' | System | 24 Aug 2020 18:48:05 |
| | System | 24 Aug 2020 18:48:05 |

US3172224

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:33:17

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-24T14:47:52', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'c4dbd9c4-ea29-466e-b6d1-a9b62d7c081e' User entered 'None (0)' | System | 24 Aug 2020 18:48:05 |
| | System | 24 Aug 2020 18:48:05 |

US3172224

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:33:17

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-24T14:47:54', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'c4dbd9c4-ea29-466e-b6d1-a9b62d7c081e' User entered 'None (0)' | System | 24 Aug 2020 18:48:05 |
| | System | 24 Aug 2020 18:48:05 |

US3172224

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:33:17

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-24T14:47:55', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'c4dbd9c4-ea29-466e-b6d1-a9b62d7c081e' User entered 'None (0)' | System | 24 Aug 2020 18:48:05 |
| | System | 24 Aug 2020 18:48:05 |

US3172224

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:33:17

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-24T14:47:57', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'c4dbd9c4-ea29-466e-b6d1-a9b62d7c081e' User entered 'None (0)' | System | 24 Aug 2020 18:48:05 |
| | System | 24 Aug 2020 18:48:05 |

US3172224

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-24T14:47:58', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'c4dbd9c4-ea29-466e-b6d1-a9b62d7c081e' User entered 'No (N)' | System | 24 Aug 2020 18:48:05 |
| | System | 24 Aug 2020 18:48:05 |

US3172224

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:33:17

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-24T14:48:00', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'c4dbd9c4-ea29-466e-b6d1-a9b62d7c081e' User entered '24 Aug 2020 14:48' | System | 24 Aug 2020 18:48:05 |
| | System | 24 Aug 2020 18:48:05 |

US3172224

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:33:17

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| User entered '24 Aug 2020 12:00' | System | 19 Aug 2020 20:51:16 |

US3172224

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:33:17

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| User entered '25 Aug 2020 11:59' | System | 19 Aug 2020 20:51:16 |

US3172224

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| Data entry locked. | System | 19 Aug 2020 20:51:16 |
| User entered 'Day 7' | System | 19 Aug 2020 20:51:16 |

US3172224

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:33:17

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-25T18:06:40', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '65034a34-242c-4c64-b6ce-6b019d2ac199' User entered 'None (0)' | System | 25 Aug 2020 22:06:54 |
| | System | 25 Aug 2020 22:06:54 |

US3172224

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:33:17

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-25T18:06:41', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '65034a34-242c-4c64-b6ce-6b019d2ac199' User entered 'None (0)' | System | 25 Aug 2020 22:06:54 |
| | System | 25 Aug 2020 22:06:54 |

US3172224

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:33:17

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-25T18:06:42', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '65034a34-242c-4c64-b6ce-6b019d2ac199' User entered 'None (0)' | System | 25 Aug 2020 22:06:54 |
| | System | 25 Aug 2020 22:06:54 |

US3172224

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:33:17

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-25T18:06:44', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '65034a34-242c-4c64-b6ce-6b019d2ac199' User entered 'None (0)' | System | 25 Aug 2020 22:06:54 |
| | System | 25 Aug 2020 22:06:54 |

US3172224

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:33:17

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-25T18:06:45', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '65034a34-242c-4c64-b6ce-6b019d2ac199' User entered 'None (0)' | System | 25 Aug 2020 22:06:54 |
| | System | 25 Aug 2020 22:06:54 |

US3172224

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:33:17

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-25T18:06:46', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '65034a34-242c-4c64-b6ce-6b019d2ac199' User entered 'None (0)' | System | 25 Aug 2020 22:06:54 |
| | System | 25 Aug 2020 22:06:54 |

US3172224

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-25T18:06:49', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '65034a34-242c-4c64-b6ce-6b019d2ac199' User entered 'No (N)' | System | 25 Aug 2020 22:06:54 |
| | System | 25 Aug 2020 22:06:54 |

US3172224

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:33:17

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-25T18:06:52', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '65034a34-242c-4c64-b6ce-6b019d2ac199' User entered '25 Aug 2020 18:06' | System | 25 Aug 2020 22:06:54 |
| | System | 25 Aug 2020 22:06:54 |

US3172224

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:33:17

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| User entered '25 Aug 2020 12:00' | System | 19 Aug 2020 20:51:16 |

US3172224

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:33:17

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| User entered '26 Aug 2020 11:59' | System | 19 Aug 2020 20:51:16 |

US3172224

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:17

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'Yes (Y)' | Jessie Downs (b) (4) (b) (4) | 31 Aug 2020 16:23:29 |

US3172224

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:17

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered '26 Aug 2020' | Jessie Downs (b) (4) (b) (4) | 31 Aug 2020 16:23:29 |

US3172224

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:17

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'Contact Made (CONTACT MADE)' | Jessie Downs (b) (4) (b) (4) | 31 Aug 2020 16:23:29 |

US3172224

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:17

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered empty. | Jessie Downs (b) (4) (b) (4) | 31 Aug 2020 16:23:29 |

US3172224

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:17

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'Yes (Y)' | Jessie Downs (b) (4) (b) (4) | 31 Aug 2020 16:23:35 |

US3172224

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:17

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User entered 'I' | System | 31 Aug 2020 16:23:35 |

US3172224

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:17

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'Yes (Y)' | Jessie Downs (b) (4) (b) (4) | 17 Sep 2020 19:05:37 |

US3172224

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:17

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered '02 Sep 2020' | Jessie Downs (b) (4) (b) (4) | 17 Sep 2020 19:05:37 |

US3172224

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:17

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'Contact Made (CONTACT MADE)' | Jessie Downs (b) (4) (b) (4) | 17 Sep 2020 19:05:37 |

US3172224

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:17

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered empty. | Jessie Downs (b) (4) (b) (4) | 17 Sep 2020 19:05:37 |

US3172224

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:17

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'Yes (Y)' | Jessie Downs (b) (4) (b) (4) | 16 Sep 2020 19:37:38 |

US3172224

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:17

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User entered 'I' | System | 16 Sep 2020 19:37:38 |

US3172224

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:17

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'Yes (Y)' | Jessie Downs (b) (4) (b) (4) | 17 Sep 2020 19:07:06 |

US3172224

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:17

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| User entered '09 Sep 2020' | Jessie Downs (b) (4) | 17 Sep 2020 19:07:06 |
| | (b) (4) | |

US3172224

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:17

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'Contact Made (CONTACT MADE)' | Jessie Downs (b) (4) (b) (4) | 17 Sep 2020 19:07:06 |

US3172224

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:17

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered empty. | Jessie Downs (b) (4) (b) (4) | 17 Sep 2020 19:07:06 |

US3172224

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:17

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'Yes (Y)' | Jessie Downs (b) (4) (b) (4) | 16 Sep 2020 19:37:50 |

US3172224

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:17

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User entered 'I' | System | 16 Sep 2020 19:37:50 |

US3172224

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:33:17

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'Yes (Y)' | Jessie Downs (b) (4) (b) (4) | 16 Sep 2020 19:40:08 |

US3172224

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered '16 Sep 2020' | Jessie Downs (b) (4) (b) (4) | 16 Sep 2020 19:40:08 |

US3172224

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:33:17

Was visit performed at the participant's home or at the clinic?

| Audit | User | Time (GMT) |
|--------------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'Clinic (Clinic)' | Jessie Downs (b) (4) (b) (4) | 16 Sep 2020 19:40:08 |

US3172224

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:33:17

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User entered 'VISIT2' | System | 16 Sep 2020 19:40:08 |

US3172224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User accepted default value 'Pre-Dose (PREDOSE)' | Jessie Downs (b) (4) (b) (4) | 17 Sep 2020 19:19:26 |

US3172224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

Were vital signs assessed?

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'Yes (Y)' | Jessie Downs (b) (4) (b) (4) | 17 Sep 2020 19:19:26 |

US3172224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered '16 Sep 2020' | Jessie Downs (b) (4) (b) (4) | 17 Sep 2020 19:19:26 |

US3172224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered '14:25' | Jessie Downs (b) (4) (b) (4) | 17 Sep 2020 19:19:26 |

US3172224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User entered '16 Sep 2020 14:25' | System | 17 Sep 2020 19:19:26 |

US3172224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered '37.1' C | Jessie Downs (b) (4) (b) (4) | 17 Sep 2020 19:19:26 |

US3172224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'Oral (Oral)' | Jessie Downs (b) (4) (b) (4) | 17 Sep 2020 19:19:26 |

US3172224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered empty. | Jessie Downs (b) (4) (b) (4) | 17 Sep 2020 19:19:26 |

US3172224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered '95' | Jessie Downs (b) (4) (b) (4) | 17 Sep 2020 19:19:26 |

US3172224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User entered 'bpm' | System | 17 Sep 2020 19:19:26 |

US3172224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered '16' | Jessie Downs (b) (4) (b) (4) | 17 Sep 2020 19:19:26 |

US3172224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User entered 'breaths/min' | System | 17 Sep 2020 19:19:26 |

US3172224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered '91' | Jessie Downs (b) (4) (b) (4) | 17 Sep 2020 19:19:26 |

US3172224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User entered 'mmHg' | System | 17 Sep 2020 19:19:26 |

US3172224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered '75' | Jessie Downs (b) (4) (b) (4) | 17 Sep 2020 19:19:26 |

US3172224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User entered 'mmHg' | System | 17 Sep 2020 19:19:26 |

US3172224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User accepted default value 'Post-Dose (POSTDOSE)' | Jessie Downs (b) (4) (b) (4) | 17 Sep 2020 19:19:26 |

US3172224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

Were vital signs assessed?

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'Yes (Y)' | Jessie Downs (b) (4) (b) (4) | 17 Sep 2020 19:19:26 |

US3172224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered '16 Sep 2020' | Jessie Downs (b) (4) (b) (4) | 17 Sep 2020 19:19:26 |

US3172224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered '15:58' | Jessie Downs (b) (4) (b) (4) | 17 Sep 2020 19:19:26 |

US3172224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User entered '16 Sep 2020 15:58' | System | 17 Sep 2020 19:19:26 |

US3172224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered '37.1' C | Jessie Downs (b) (4) (b) (4) | 17 Sep 2020 19:19:26 |

US3172224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'Oral (Oral)' | Jessie Downs (b) (4) (b) (4) | 17 Sep 2020 19:19:26 |

US3172224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered empty. | Jessie Downs (b) (4) (b) (4) | 17 Sep 2020 19:19:26 |

US3172224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered '91' | Jessie Downs (b) (4) (b) (4) | 17 Sep 2020 19:19:26 |

US3172224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User entered 'bpm' | System | 17 Sep 2020 19:19:26 |

US3172224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered '14' | Jessie Downs (b) (4) (b) (4) | 17 Sep 2020 19:19:26 |

US3172224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User entered 'breaths/min' | System | 17 Sep 2020 19:19:26 |

US3172224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered '121' | Jessie Downs (b) (4) (b) (4) | 17 Sep 2020 19:19:26 |

US3172224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User entered 'mmHg' | System | 17 Sep 2020 19:19:26 |

US3172224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered '76' | Jessie Downs (b) (4) (b) (4) | 17 Sep 2020 19:19:26 |

US3172224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User entered 'mmHg' | System | 17 Sep 2020 19:19:26 |

US3172224

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:33:17

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'Yes (Y)' | Jessie Downs (b) (4) (b) (4) | 17 Sep 2020 19:07:32 |

US3172224

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:33:17

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered '16 Sep 2020' | Jessie Downs (b) (4) (b) (4) | 17 Sep 2020 19:07:32 |

US3172224

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:33:17

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'Yes (Y)' | Jessie Downs (b) (4) (b) (4) | 16 Sep 2020 19:38:45 |

US3172224

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:33:17

If No, reason not given

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered empty. | Jessie Downs (b) (4) (b) (4) | 16 Sep 2020 19:38:45 |

US3172224

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered empty. | Jessie Downs (b) (4) (b) (4) | 16 Sep 2020 19:38:45 |

US3172224

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:33:17

[What was the study treatment?](#)

| Audit | User | Time (GMT) |
|-------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User entered 'MRNA-1273 OR PLACEBO' | System | 16 Sep 2020 19:38:45 |

US3172224

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:33:17

What was the treatment date? (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered '16 Sep 2020' | Jessie Downs (b) (4) (b) (4) | 16 Sep 2020 19:38:45 |

US3172224

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered '15:28' | Jessie Downs (b) (4) (b) (4) | 16 Sep 2020 19:38:45 |

US3172224

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User entered '16 Sep 2020 15:28' | System | 16 Sep 2020 19:38:45 |

US3172224

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|--------------------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'Right Arm (RIGHT ARM)' | Jessie Downs (b) (4) (b) (4) | 16 Sep 2020 19:38:45 |

US3172224

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:33:17

What was the frequency of the study treatment dosing?

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User entered 'ONCE' | System | 16 Sep 2020 19:38:45 |

US3172224

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:33:17

What was the route of administration for the study treatment?

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User entered 'INTRAMUSCULAR' | System | 16 Sep 2020 19:38:45 |

US3172224

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:33:17

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'Yes (Y)' | Jessie Downs (b) (4) (b) (4) | 17 Sep 2020 19:07:51 |

US3172224

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:33:17

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered '16 Sep 2020' | Jessie Downs (b) (4) (b) (4) | 17 Sep 2020 19:07:51 |

US3172224

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:33:17

Collection time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered '15:17' | Jessie Downs (b) (4) (b) (4) | 17 Sep 2020 19:07:51 |

US3172224

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User entered '16 Sep 2020 15:17' | System | 17 Sep 2020 19:07:51 |

US3172224

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:33:17

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered '16 Sep 2020' | Jessie Downs (b) (4) (b) (4) | 17 Sep 2020 19:08:34 |

US3172224

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:33:17

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | Jessie Downs (b) (4) (b) (4) | 17 Sep 2020 19:08:34 |

US3172224

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:33:17

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'Yes (Y)' | Jessie Downs (b) (4) (b) (4) | 17 Sep 2020 19:08:34 |

US3172224

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:33:17

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered '15:13' | Jessie Downs (b) (4) (b) (4) | 17 Sep 2020 19:08:34 |

US3172224

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User entered '16 Sep 2020 15:13' | System | 17 Sep 2020 19:08:34 |

US3172224

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:33:17

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | Jessie Downs (b) (4) (b) (4) | 17 Sep 2020 19:08:34 |

US3172224

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:33:17

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'Yes (Y)' | Jessie Downs (b) (4) (b) (4) | 17 Sep 2020 19:08:34 |

US3172224

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:33:17

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered '15:13' | Jessie Downs (b) (4) (b) (4) | 17 Sep 2020 19:08:34 |

US3172224

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User entered '16 Sep 2020 15:13' | System | 17 Sep 2020 19:08:34 |

US3172224

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:17

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'Yes (Y)' | Jessie Downs (b) (4) (b) (4) | 17 Sep 2020 19:07:14 |

US3172224

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:17

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User entered '1' | System | 17 Sep 2020 19:07:14 |

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| Data entry locked. | System | 16 Sep 2020 19:38:45 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 16 Sep 2020 19:38:45 |

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-16T15:58:11', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'e70509fc-72ac-4dd1-ba9b-b7249a87bf0d' User entered 'Yes (Y)' | System | 16 Sep 2020 19:58:27 |
| | System | 16 Sep 2020 19:58:27 |

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-16T15:58:17', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'e70509fc-72ac-4dd1-ba9b-b7249a87bf0d' User entered '98.9' | System | 16 Sep 2020 19:58:27 |
| | System | 16 Sep 2020 19:58:27 |

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-16T15:58:19', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'e70509fc-72ac-4dd1-ba9b-b7249a87bf0d' User entered 'No (N)' | System | 16 Sep 2020 19:58:27 |
| | System | 16 Sep 2020 19:58:27 |

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-16T15:58:22', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'e70509fc-72ac-4dd1-ba9b-b7249a87bf0d' User entered '16 Sep 2020 15:58' | System | 16 Sep 2020 19:58:27 |
| | System | 16 Sep 2020 19:58:27 |

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| User entered '16 Sep 2020 15:48' | System | 16 Sep 2020 19:38:45 |

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| User entered '16 Sep 2020 18:18' | System | 16 Sep 2020 19:38:45 |

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| Data entry locked. | System | 16 Sep 2020 19:38:45 |
| User entered 'Day 1, after vaccination (at home)' | System | 16 Sep 2020 19:38:45 |

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-16T19:34:12', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '17ee72af-6a66-41ed-8004-4e62ed7e0193' | System | 16 Sep 2020 23:34:28 |
| User entered 'Yes (Y)' | System | 16 Sep 2020 23:34:28 |

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-16T19:34:20', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '17ee72af-6a66-41ed-8004-4e62ed7e0193' User entered '97.7' | System | 16 Sep 2020 23:34:28 |
| | System | 16 Sep 2020 23:34:28 |

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-16T19:34:23', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '17ee72af-6a66-41ed-8004-4e62ed7e0193' | System | 16 Sep 2020 23:34:28 |
| User entered 'No (N)' | System | 16 Sep 2020 23:34:28 |

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-16T19:34:27', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '17ee72af-6a66-41ed-8004-4e62ed7e0193' User entered '16 Sep 2020 19:34' | System | 16 Sep 2020 23:34:28 |
| | System | 16 Sep 2020 23:34:28 |

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| User entered '16 Sep 2020 19:13' | System | 16 Sep 2020 19:38:45 |

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| User entered '17 Sep 2020 11:59' | System | 16 Sep 2020 19:38:45 |

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| Data entry locked. | System | 16 Sep 2020 19:38:45 |
| User entered 'Day 2' | System | 16 Sep 2020 19:38:45 |

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:33:17

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-17T12:03:01', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'ba168a0a-2be3-45ac-a703-947e1662a563' | System | 17 Sep 2020 16:04:46 |
| User entered 'Yes (Y)' | System | 17 Sep 2020 16:04:46 |

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:33:17

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-17T12:03:07', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'ba168a0a-2be3-45ac-a703-947e1662a563' User entered '98.8' | System | 17 Sep 2020 16:04:46 |
| | System | 17 Sep 2020 16:04:46 |

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-17T12:03:12', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'ba168a0a-2be3-45ac-a703-947e1662a563' User entered 'No (N)' | System | 17 Sep 2020 16:04:46 |
| | System | 17 Sep 2020 16:04:46 |

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:33:17

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-17T12:03:15', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'ba168a0a-2be3-45ac-a703-947e1662a563' | System | 17 Sep 2020 16:04:46 |
| User entered '17 Sep 2020 12:03' | System | 17 Sep 2020 16:04:46 |

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:33:17

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| User entered '17 Sep 2020 12:00' | System | 16 Sep 2020 19:38:45 |

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:33:17

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| User entered '18 Sep 2020 11:59' | System | 16 Sep 2020 19:38:45 |

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| Data entry locked. | System | 16 Sep 2020 19:38:45 |
| User entered 'Day 3' | System | 16 Sep 2020 19:38:45 |

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:33:17

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-18T12:07:53', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '2b96f4e1-0295-47d3-bb4d-c46a259a5d6c' User entered 'Yes (Y)' | System | 18 Sep 2020 16:08:11 |
| | System | 18 Sep 2020 16:08:11 |

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:33:17

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-18T12:08:02', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '2b96f4e1-0295-47d3-bb4d-c46a259a5d6c' User entered '98.5' | System | 18 Sep 2020 16:08:11 |
| | System | 18 Sep 2020 16:08:11 |

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-18T12:08:05', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '2b96f4e1-0295-47d3-bb4d-c46a259a5d6c' User entered 'No (N)' | System | 18 Sep 2020 16:08:11 |
| | System | 18 Sep 2020 16:08:11 |

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:33:17

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-18T12:08:07', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '2b96f4e1-0295-47d3-bb4d-c46a259a5d6c' User entered '18 Sep 2020 12:08' | System | 18 Sep 2020 16:08:11 |
| | System | 18 Sep 2020 16:08:11 |

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:33:17

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| User entered '18 Sep 2020 12:00' | System | 16 Sep 2020 19:38:45 |

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:33:17

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| User entered '19 Sep 2020 11:59' | System | 16 Sep 2020 19:38:45 |

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| Data entry locked. | System | 16 Sep 2020 19:38:45 |
| User entered 'Day 4' | System | 16 Sep 2020 19:38:45 |

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:33:17

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-19T16:33:44', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '8fc0a9aa-091b-49a0-b2f3-590e64ee1380' User entered 'Yes (Y)' | System | 19 Sep 2020 20:33:56 |
| | System | 19 Sep 2020 20:33:56 |

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:33:17

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-19T16:33:50', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '8fc0a9aa-091b-49a0-b2f3-590e64ee1380' User entered '98.8' | System | 19 Sep 2020 20:33:56 |
| | System | 19 Sep 2020 20:33:56 |

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-19T16:33:52', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '8fc0a9aa-091b-49a0-b2f3-590e64ee1380' | System | 19 Sep 2020 20:33:56 |
| User entered 'No (N)' | System | 19 Sep 2020 20:33:56 |

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:33:17

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-19T16:33:55', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '8fc0a9aa-091b-49a0-b2f3-590e64ee1380' User entered '19 Sep 2020 16:33' | System | 19 Sep 2020 20:33:56 |
| | System | 19 Sep 2020 20:33:56 |

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:33:17

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| User entered '19 Sep 2020 12:00' | System | 16 Sep 2020 19:38:45 |

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:33:17

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| User entered '20 Sep 2020 11:59' | System | 16 Sep 2020 19:38:45 |

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| Data entry locked. | System | 16 Sep 2020 19:38:45 |
| User entered 'Day 5' | System | 16 Sep 2020 19:38:45 |

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:33:17

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-20T12:06:47', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '06f2d214-beb0-4129-a66a-27bbb9c8f076' User entered 'Yes (Y)' | System | 20 Sep 2020 16:07:00 |
| | System | 20 Sep 2020 16:07:00 |

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:33:17

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-20T12:06:54', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '06f2d214-beb0-4129-a66a-27bbb9c8f076' User entered '98.4' | System | 20 Sep 2020 16:07:00 |
| | System | 20 Sep 2020 16:07:00 |

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-20T12:06:56', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '06f2d214-beb0-4129-a66a-27bbb9c8f076' User entered 'No (N)' | System | 20 Sep 2020 16:07:00 |
| | System | 20 Sep 2020 16:07:00 |

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:33:17

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-20T12:06:58', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '06f2d214-beb0-4129-a66a-27bbb9c8f076' User entered '20 Sep 2020 12:06' | System | 20 Sep 2020 16:07:00 |
| | System | 20 Sep 2020 16:07:00 |

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:33:17

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| User entered '20 Sep 2020 12:00' | System | 16 Sep 2020 19:38:45 |

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:33:17

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| User entered '21 Sep 2020 11:59' | System | 16 Sep 2020 19:38:45 |

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| Data entry locked. | System | 16 Sep 2020 19:38:45 |
| User entered 'Day 6' | System | 16 Sep 2020 19:38:45 |

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:33:17

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-21T12:51:23', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'b9facc29-efdd-4720-b633-8a495149d2c3' User entered 'Yes (Y)' | System | 21 Sep 2020 16:51:37 |
| | System | 21 Sep 2020 16:51:37 |

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:33:17

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-21T12:51:29', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'b9facc29-efdd-4720-b633-8a495149d2c3' User entered '98.8' | System | 21 Sep 2020 16:51:37 |
| | System | 21 Sep 2020 16:51:37 |

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-21T12:51:31', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'b9facc29-efdd-4720-b633-8a495149d2c3' User entered 'No (N)' | System | 21 Sep 2020 16:51:37 |
| | System | 21 Sep 2020 16:51:37 |

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:33:17

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-21T12:51:34', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'b9facc29-efdd-4720-b633-8a495149d2c3' User entered '21 Sep 2020 12:51' | System | 21 Sep 2020 16:51:37 |
| | System | 21 Sep 2020 16:51:37 |

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:33:17

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| User entered '21 Sep 2020 12:00' | System | 16 Sep 2020 19:38:45 |

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:33:17

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| User entered '22 Sep 2020 11:59' | System | 16 Sep 2020 19:38:45 |

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| Data entry locked. | System | 16 Sep 2020 19:38:45 |
| User entered 'Day 7' | System | 16 Sep 2020 19:38:45 |

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:33:17

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-22T15:52:51', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '1a182d4d-dab2-450d-9892-e7bb6f96841e' User entered 'Yes (Y)' | System | 22 Sep 2020 19:53:18 |
| | System | 22 Sep 2020 19:53:18 |

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:33:17

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-22T15:52:57', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '1a182d4d-dab2-450d-9892-e7bb6f96841e' User entered '98.8' | System | 22 Sep 2020 19:53:18 |
| | System | 22 Sep 2020 19:53:18 |

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-22T15:53:01', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '1a182d4d-dab2-450d-9892-e7bb6f96841e' User entered 'Yes (Y)' | System | 22 Sep 2020 19:53:18 |
| | System | 22 Sep 2020 19:53:18 |

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Data updated in conmed log' (Site from System). | (b) (4), (b) (6) | 29 Sep 2020 03:56:53 |
| User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' | Mariete Rendon (b) (4) | 25 Sep 2020 17:17:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-22T15:53:11', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '1a182d4d-dab2-450d-9892-e7bb6f96841e' | System | 22 Sep 2020 19:53:18 |
| User entered '1' | System | 22 Sep 2020 19:53:18 |

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:33:17

To **PREVENT** pain or fever from occurring

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-22T15:53:11', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '1a182d4d-dab2-450d-9892-e7bb6f96841e' User entered '0' | System | 22 Sep 2020 19:53:18 |
| | System | 22 Sep 2020 19:53:18 |

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:33:17

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-22T15:53:13', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '1a182d4d-dab2-450d-9892-e7bb6f96841e' User entered '22 Sep 2020 15:53' | System | 22 Sep 2020 19:53:18 |
| | System | 22 Sep 2020 19:53:18 |

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:33:17

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| User entered '22 Sep 2020 12:00' | System | 16 Sep 2020 19:38:45 |

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:33:17

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| User entered '23 Sep 2020 11:59' | System | 16 Sep 2020 19:38:45 |

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| Data entry locked. | System | 22 Sep 2020 19:53:18 |
| User entered 'Day 8' | System | 22 Sep 2020 19:53:18 |

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:33:17

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-23T12:34:05', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'aeaf8904-b8db-422a-962b-5c97396204a5' User entered 'Yes (Y)' | System | 23 Sep 2020 16:34:20 |
| | System | 23 Sep 2020 16:34:20 |

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:33:17

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-23T12:34:10', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'aeaf8904-b8db-422a-962b-5c97396204a5' User entered '97.6' | System | 23 Sep 2020 16:34:20 |
| | System | 23 Sep 2020 16:34:20 |

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-23T12:34:12', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'aeaf8904-b8db-422a-962b-5c97396204a5' User entered 'No (N)' | System | 23 Sep 2020 16:34:20 |
| | System | 23 Sep 2020 16:34:20 |

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:33:17

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-23T12:34:14', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'aeaf8904-b8db-422a-962b-5c97396204a5' User entered '23 Sep 2020 12:34' | System | 23 Sep 2020 16:34:20 |
| | System | 23 Sep 2020 16:34:20 |

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:33:17

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| User entered '23 Sep 2020 12:00' | System | 22 Sep 2020 19:53:18 |

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 09 Jun 2021 15:33:17

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| User entered '24 Sep 2020 11:59' | System | 22 Sep 2020 19:53:18 |

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| Data entry locked. | System | 16 Sep 2020 19:38:45 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 16 Sep 2020 19:38:45 |

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-16T15:58:29', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'bc95bf49-82ef-4f00-9165-2cfa6fa7b09c' | System | 16 Sep 2020 19:58:44 |
| User entered 'None (1)' | System | 16 Sep 2020 19:58:44 |

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-16T15:58:35', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'bc95bf49-82ef-4f00-9165-2cfa6fa7b09c' User entered 'No (N)' | System | 16 Sep 2020 19:58:44 |
| | System | 16 Sep 2020 19:58:44 |

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-16T15:58:37', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'bc95bf49-82ef-4f00-9165-2cfa6fa7b09c' User entered 'No (N)' | System | 16 Sep 2020 19:58:44 |
| | System | 16 Sep 2020 19:58:44 |

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-16T15:58:40', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'bc95bf49-82ef-4f00-9165-2cfa6fa7b09c' User entered 'None (1)' | System | 16 Sep 2020 19:58:44 |
| | System | 16 Sep 2020 19:58:44 |

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-16T15:58:42', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'bc95bf49-82ef-4f00-9165-2cfa6fa7b09c' User entered '16 Sep 2020 15:58' | System | 16 Sep 2020 19:58:44 |
| | System | 16 Sep 2020 19:58:44 |

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| User entered '16 Sep 2020 15:48' | System | 16 Sep 2020 19:38:45 |

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| User entered '16 Sep 2020 18:18' | System | 16 Sep 2020 19:38:45 |

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| Data entry locked. | System | 16 Sep 2020 19:38:45 |
| User entered 'Day 1, after vaccination (at home)' | System | 16 Sep 2020 19:38:45 |

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-16T19:34:32', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'da78f0b6-111b-42c0-b10a-ab3bf6dd5a90' User entered 'None (1)' | System | 16 Sep 2020 23:34:43 |
| | System | 16 Sep 2020 23:34:43 |

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-16T19:34:34', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'da78f0b6-111b-42c0-b10a-ab3bf6dd5a90' User entered 'No (N)' | System | 16 Sep 2020 23:34:43 |
| | System | 16 Sep 2020 23:34:43 |

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-16T19:34:36', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'da78f0b6-111b-42c0-b10a-ab3bf6dd5a90' User entered 'No (N)' | System | 16 Sep 2020 23:34:43 |
| | System | 16 Sep 2020 23:34:43 |

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-16T19:34:39', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'da78f0b6-111b-42c0-b10a-ab3bf6dd5a90' User entered 'None (1)' | System | 16 Sep 2020 23:34:43 |
| | System | 16 Sep 2020 23:34:43 |

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-16T19:34:41', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'da78f0b6-111b-42c0-b10a-ab3bf6dd5a90' User entered '16 Sep 2020 19:34' | System | 16 Sep 2020 23:34:43 |
| | System | 16 Sep 2020 23:34:43 |

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| User entered '16 Sep 2020 19:13' | System | 16 Sep 2020 19:38:45 |

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| User entered '17 Sep 2020 11:59' | System | 16 Sep 2020 19:38:45 |

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| Data entry locked. | System | 16 Sep 2020 19:38:45 |
| User entered 'Day 2' | System | 16 Sep 2020 19:38:45 |

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:33:17

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-17T12:03:19', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '85dfc8f7-9554-4bcb-8ecb-6a28d0f98d26' | System | 17 Sep 2020 16:04:54 |
| User entered 'None (1)' | System | 17 Sep 2020 16:04:54 |

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:33:17

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-17T12:03:21', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '85dfc8f7-9554-4bcb-8ecb-6a28d0f98d26' User entered 'No (N)' | System | 17 Sep 2020 16:04:54 |
| | System | 17 Sep 2020 16:04:54 |

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-17T12:03:24', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '85dfc8f7-9554-4bcb-8ecb-6a28d0f98d26' User entered 'No (N)' | System | 17 Sep 2020 16:04:54 |
| | System | 17 Sep 2020 16:04:54 |

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:33:17

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-17T12:03:32', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '85dfc8f7-9554-4bcb-8ecb-6a28d0f98d26' | System | 17 Sep 2020 16:04:54 |
| User entered 'None (1)' | System | 17 Sep 2020 16:04:54 |

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:33:17

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-17T12:03:35', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '85dfc8f7-9554-4bcb-8ecb-6a28d0f98d26' User entered '17 Sep 2020 12:03' | System | 17 Sep 2020 16:04:54 |
| | System | 17 Sep 2020 16:04:54 |

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:33:17

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| User entered '17 Sep 2020 12:00' | System | 16 Sep 2020 19:38:45 |

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:33:17

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| User entered '18 Sep 2020 11:59' | System | 16 Sep 2020 19:38:45 |

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| Data entry locked. | System | 16 Sep 2020 19:38:45 |
| User entered 'Day 3' | System | 16 Sep 2020 19:38:45 |

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:33:17

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-18T12:08:12', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '4d3d0497-a149-4adc-866c-35ab2e145fa1' User entered 'None (1)' | System | 18 Sep 2020 16:08:24 |
| | System | 18 Sep 2020 16:08:24 |

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:33:17

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-18T12:08:15', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '4d3d0497-a149-4adc-866c-35ab2e145fa1' User entered 'No (N)' | System | 18 Sep 2020 16:08:24 |
| | System | 18 Sep 2020 16:08:24 |

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-18T12:08:17', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '4d3d0497-a149-4adc-866c-35ab2e145fa1' User entered 'No (N)' | System | 18 Sep 2020 16:08:24 |
| | System | 18 Sep 2020 16:08:24 |

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:33:17

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-18T12:08:19', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '4d3d0497-a149-4adc-866c-35ab2e145fa1' User entered 'None (1)' | System | 18 Sep 2020 16:08:24 |
| | System | 18 Sep 2020 16:08:24 |

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:33:17

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-18T12:08:21', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '4d3d0497-a149-4adc-866c-35ab2e145fa1' User entered '18 Sep 2020 12:08' | System | 18 Sep 2020 16:08:24 |
| | System | 18 Sep 2020 16:08:24 |

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:33:17

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| User entered '18 Sep 2020 12:00' | System | 16 Sep 2020 19:38:45 |

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:33:17

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| User entered '19 Sep 2020 11:59' | System | 16 Sep 2020 19:38:45 |

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| Data entry locked. | System | 16 Sep 2020 19:38:45 |
| User entered 'Day 4' | System | 16 Sep 2020 19:38:45 |

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:33:17

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-19T16:33:58', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '91aeca53-12e9-4a24-952f-4cfcc628daab' User entered 'None (1)' | System | 19 Sep 2020 20:34:08 |
| | System | 19 Sep 2020 20:34:08 |

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:33:17

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-19T16:34:00', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '91aeca53-12e9-4a24-952f-4cfcc628daab' User entered 'No (N)' | System | 19 Sep 2020 20:34:08 |
| | System | 19 Sep 2020 20:34:08 |

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-19T16:34:02', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '91aeca53-12e9-4a24-952f-4cfcc628daab' User entered 'No (N)' | System | 19 Sep 2020 20:34:08 |
| | System | 19 Sep 2020 20:34:08 |

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:33:17

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-19T16:34:03', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '91aeca53-12e9-4a24-952f-4cfcc628daab' User entered 'None (1)' | System | 19 Sep 2020 20:34:08 |
| | System | 19 Sep 2020 20:34:08 |

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:33:17

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-19T16:34:06', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '91aeca53-12e9-4a24-952f-4cfcc628daab' User entered '19 Sep 2020 16:34' | System | 19 Sep 2020 20:34:08 |
| | System | 19 Sep 2020 20:34:08 |

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:33:17

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| User entered '19 Sep 2020 12:00' | System | 16 Sep 2020 19:38:45 |

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:33:17

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| User entered '20 Sep 2020 11:59' | System | 16 Sep 2020 19:38:45 |

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| Data entry locked. | System | 16 Sep 2020 19:38:45 |
| User entered 'Day 5' | System | 16 Sep 2020 19:38:45 |

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:33:17

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-20T12:07:02', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '27be92a2-f762-4e85-a4a6-9f0d569cb559' | System | 20 Sep 2020 16:07:16 |
| User entered 'None (1)' | System | 20 Sep 2020 16:07:16 |

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:33:17

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-20T12:07:04', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '27be92a2-f762-4e85-a4a6-9f0d569cb559' User entered 'No (N)' | System | 20 Sep 2020 16:07:16 |
| | System | 20 Sep 2020 16:07:16 |

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-20T12:07:07', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '27be92a2-f762-4e85-a4a6-9f0d569cb559' User entered 'No (N)' | System | 20 Sep 2020 16:07:16 |
| | System | 20 Sep 2020 16:07:16 |

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:33:17

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-20T12:07:09', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '27be92a2-f762-4e85-a4a6-9f0d569cb559' | System | 20 Sep 2020 16:07:16 |
| User entered 'None (1)' | System | 20 Sep 2020 16:07:16 |

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:33:17

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-20T12:07:11', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '27be92a2-f762-4e85-a4a6-9f0d569cb559' User entered '20 Sep 2020 12:07' | System | 20 Sep 2020 16:07:16 |
| | System | 20 Sep 2020 16:07:16 |

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:33:17

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| User entered '20 Sep 2020 12:00' | System | 16 Sep 2020 19:38:45 |

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:33:17

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| User entered '21 Sep 2020 11:59' | System | 16 Sep 2020 19:38:45 |

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| Data entry locked. | System | 16 Sep 2020 19:38:45 |
| User entered 'Day 6' | System | 16 Sep 2020 19:38:45 |

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:33:17

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-21T12:51:39', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '877d2458-af43-4f2e-bf19-50a3154ee34f' User entered 'None (1)' | System | 21 Sep 2020 16:51:49 |
| | System | 21 Sep 2020 16:51:49 |

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:33:17

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-21T12:51:41', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '877d2458-af43-4f2e-bf19-50a3154ee34f' User entered 'No (N)' | System | 21 Sep 2020 16:51:49 |
| | System | 21 Sep 2020 16:51:49 |

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-21T12:51:43', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '877d2458-af43-4f2e-bf19-50a3154ee34f' User entered 'No (N)' | System | 21 Sep 2020 16:51:49 |
| | System | 21 Sep 2020 16:51:49 |

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:33:17

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-21T12:51:45', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '877d2458-af43-4f2e-bf19-50a3154ee34f' User entered 'None (1)' | System | 21 Sep 2020 16:51:49 |
| | System | 21 Sep 2020 16:51:49 |

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:33:17

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-21T12:51:47', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '877d2458-af43-4f2e-bf19-50a3154ee34f' User entered '21 Sep 2020 12:51' | System | 21 Sep 2020 16:51:49 |
| | System | 21 Sep 2020 16:51:49 |

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:33:17

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| User entered '21 Sep 2020 12:00' | System | 16 Sep 2020 19:38:45 |

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:33:17

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| User entered '22 Sep 2020 11:59' | System | 16 Sep 2020 19:38:45 |

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| Data entry locked. | System | 16 Sep 2020 19:38:45 |
| User entered 'Day 7' | System | 16 Sep 2020 19:38:45 |

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:33:17

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-22T15:53:16', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'c6989f82-6144-40de-824d-b173156c6495' | System | 22 Sep 2020 19:53:35 |
| User entered 'None (1)' | System | 22 Sep 2020 19:53:35 |

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:33:17

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-22T15:53:19', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'c6989f82-6144-40de-824d-b173156c6495' | System | 22 Sep 2020 19:53:35 |
| User entered 'No (N)' | System | 22 Sep 2020 19:53:35 |

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-22T15:53:20', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'c6989f82-6144-40de-824d-b173156c6495' | System | 22 Sep 2020 19:53:35 |
| User entered 'No (N)' | System | 22 Sep 2020 19:53:35 |

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:33:17

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-22T15:53:30', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'c6989f82-6144-40de-824d-b173156c6495' | System | 22 Sep 2020 19:53:35 |
| User entered 'None (1)' | System | 22 Sep 2020 19:53:35 |

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:33:17

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-22T15:53:33', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'c6989f82-6144-40de-824d-b173156c6495' User entered '22 Sep 2020 15:53' | System | 22 Sep 2020 19:53:35 |
| | System | 22 Sep 2020 19:53:35 |

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:33:17

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| User entered '22 Sep 2020 12:00' | System | 16 Sep 2020 19:38:45 |

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:33:17

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| User entered '23 Sep 2020 11:59' | System | 16 Sep 2020 19:38:45 |

US3172224

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| Data entry locked. | System | 16 Sep 2020 19:38:45 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 16 Sep 2020 19:38:45 |

US3172224

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-16T15:58:45', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '55b6f0f0-4ff3-489a-972e-973fe9a2cf93' User entered 'None (0)' | System | 16 Sep 2020 19:59:02 |
| | System | 16 Sep 2020 19:59:02 |

US3172224

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-16T15:58:47', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '55b6f0f0-4ff3-489a-972e-973fe9a2cf93' User entered 'None (0)' | System | 16 Sep 2020 19:59:02 |
| | System | 16 Sep 2020 19:59:02 |

US3172224

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-16T15:58:48', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '55b6f0f0-4ff3-489a-972e-973fe9a2cf93' User entered 'None (0)' | System | 16 Sep 2020 19:59:02 |
| | System | 16 Sep 2020 19:59:02 |

US3172224

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-16T15:58:49', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '55b6f0f0-4ff3-489a-972e-973fe9a2cf93' User entered 'None (0)' | System | 16 Sep 2020 19:59:02 |
| | System | 16 Sep 2020 19:59:02 |

US3172224

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-16T15:58:50', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '55b6f0f0-4ff3-489a-972e-973fe9a2cf93' User entered 'None (0)' | System | 16 Sep 2020 19:59:02 |
| | System | 16 Sep 2020 19:59:02 |

US3172224

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-16T15:58:53', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '55b6f0f0-4ff3-489a-972e-973fe9a2cf93' User entered 'None (0)' | System | 16 Sep 2020 19:59:02 |
| | System | 16 Sep 2020 19:59:02 |

US3172224

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-16T15:58:55', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '55b6f0f0-4ff3-489a-972e-973fe9a2cf93' | System | 16 Sep 2020 19:59:02 |
| User entered 'No (N)' | System | 16 Sep 2020 19:59:02 |

US3172224

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-16T15:58:57', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '55b6f0f0-4ff3-489a-972e-973fe9a2cf93' | System | 16 Sep 2020 19:59:02 |
| User entered '16 Sep 2020 15:58' | System | 16 Sep 2020 19:59:02 |

US3172224

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| User entered '16 Sep 2020 15:48' | System | 16 Sep 2020 19:38:45 |

US3172224

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| User entered '16 Sep 2020 18:18' | System | 16 Sep 2020 19:38:45 |

US3172224

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| Data entry locked. | System | 16 Sep 2020 19:38:45 |
| User entered 'Day 1, after vaccination (at home)' | System | 16 Sep 2020 19:38:45 |

US3172224

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-16T19:34:46', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '2166249c-00de-4afc-bfad-df35b0503b76' User entered 'None (0)' | System | 16 Sep 2020 23:35:00 |
| | System | 16 Sep 2020 23:35:00 |

US3172224

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-16T19:34:47', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '2166249c-00de-4afc-bfad-df35b0503b76' User entered 'None (0)' | System | 16 Sep 2020 23:35:00 |
| | System | 16 Sep 2020 23:35:00 |

US3172224

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-16T19:34:48', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '2166249c-00de-4afc-bfad-df35b0503b76' User entered 'None (0)' | System | 16 Sep 2020 23:35:00 |
| | System | 16 Sep 2020 23:35:00 |

US3172224

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-16T19:34:50', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '2166249c-00de-4afc-bfad-df35b0503b76' User entered 'None (0)' | System | 16 Sep 2020 23:35:00 |
| | System | 16 Sep 2020 23:35:00 |

US3172224

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-16T19:34:51', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '2166249c-00de-4afc-bfad-df35b0503b76' User entered 'None (0)' | System | 16 Sep 2020 23:35:00 |
| | System | 16 Sep 2020 23:35:00 |

US3172224

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-16T19:34:52', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '2166249c-00de-4afc-bfad-df35b0503b76' User entered 'None (0)' | System | 16 Sep 2020 23:35:00 |
| | System | 16 Sep 2020 23:35:00 |

US3172224

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-16T19:34:55', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '2166249c-00de-4afc-bfad-df35b0503b76' User entered 'No (N)' | System | 16 Sep 2020 23:35:00 |
| | System | 16 Sep 2020 23:35:00 |

US3172224

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-16T19:34:57', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '2166249c-00de-4afc-bfad-df35b0503b76' User entered '16 Sep 2020 19:34' | System | 16 Sep 2020 23:35:00 |
| | System | 16 Sep 2020 23:35:00 |

US3172224

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| User entered '16 Sep 2020 19:13' | System | 16 Sep 2020 19:38:45 |

US3172224

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| User entered '17 Sep 2020 11:59' | System | 16 Sep 2020 19:38:45 |

US3172224

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| Data entry locked. | System | 16 Sep 2020 19:38:45 |
| User entered 'Day 2' | System | 16 Sep 2020 19:38:45 |

US3172224

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:33:17

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-17T12:03:39', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'dbcd60b6-1161-4c3e-8866-eac7b7868960' User entered 'None (0)' | System | 17 Sep 2020 16:05:03 |
| | System | 17 Sep 2020 16:05:03 |

US3172224

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:33:17

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-17T12:03:41', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'dbcd60b6-1161-4c3e-8866-eac7b7868960' User entered 'None (0)' | System | 17 Sep 2020 16:05:03 |
| | System | 17 Sep 2020 16:05:03 |

US3172224

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:33:17

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-17T12:03:42', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'dbcd60b6-1161-4c3e-8866-eac7b7868960' User entered 'None (0)' | System | 17 Sep 2020 16:05:03 |
| | System | 17 Sep 2020 16:05:03 |

US3172224

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:33:17

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-17T12:03:44', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'dbcd60b6-1161-4c3e-8866-eac7b7868960' User entered 'None (0)' | System | 17 Sep 2020 16:05:03 |
| | System | 17 Sep 2020 16:05:03 |

US3172224

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:33:17

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-17T12:03:46', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'dbcd60b6-1161-4c3e-8866-eac7b7868960' User entered 'None (0)' | System | 17 Sep 2020 16:05:03 |
| | System | 17 Sep 2020 16:05:03 |

US3172224

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:33:17

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-17T12:03:48', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'dbcd60b6-1161-4c3e-8866-eac7b7868960' User entered 'None (0)' | System | 17 Sep 2020 16:05:03 |
| | System | 17 Sep 2020 16:05:03 |

US3172224

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-17T12:03:50', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'dbcd60b6-1161-4c3e-8866-eac7b7868960' User entered 'No (N)' | System | 17 Sep 2020 16:05:03 |
| | System | 17 Sep 2020 16:05:03 |

US3172224

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:33:17

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-17T12:03:52', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'dbcd60b6-1161-4c3e-8866-eac7b7868960' User entered '17 Sep 2020 12:03' | System | 17 Sep 2020 16:05:03 |
| | System | 17 Sep 2020 16:05:03 |

US3172224

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:33:17

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| User entered '17 Sep 2020 12:00' | System | 16 Sep 2020 19:38:45 |

US3172224

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:33:17

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| User entered '18 Sep 2020 11:59' | System | 16 Sep 2020 19:38:45 |

US3172224

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| Data entry locked. | System | 16 Sep 2020 19:38:45 |
| User entered 'Day 3' | System | 16 Sep 2020 19:38:45 |

US3172224

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:33:17

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-18T12:08:25', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'f63622b6-2371-416d-9cb8-6f80238aae68' User entered 'None (0)' | System | 18 Sep 2020 16:08:41 |
| | System | 18 Sep 2020 16:08:41 |

US3172224

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:33:17

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-18T12:08:27', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'f63622b6-2371-416d-9cb8-6f80238aae68' User entered 'None (0)' | System | 18 Sep 2020 16:08:41 |
| | System | 18 Sep 2020 16:08:41 |

US3172224

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:33:17

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-18T12:08:28', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'f63622b6-2371-416d-9cb8-6f80238aae68' User entered 'None (0)' | System | 18 Sep 2020 16:08:41 |
| | System | 18 Sep 2020 16:08:41 |

US3172224

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:33:17

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-18T12:08:30', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'f63622b6-2371-416d-9cb8-6f80238aae68' User entered 'None (0)' | System | 18 Sep 2020 16:08:41 |
| | System | 18 Sep 2020 16:08:41 |

US3172224

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:33:17

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-18T12:08:31', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'f63622b6-2371-416d-9cb8-6f80238aae68' User entered 'None (0)' | System | 18 Sep 2020 16:08:41 |
| | System | 18 Sep 2020 16:08:41 |

US3172224

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:33:17

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-18T12:08:32', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'f63622b6-2371-416d-9cb8-6f80238aae68' User entered 'None (0)' | System | 18 Sep 2020 16:08:41 |
| | System | 18 Sep 2020 16:08:41 |

US3172224

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-18T12:08:34', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'f63622b6-2371-416d-9cb8-6f80238aae68' User entered 'No (N)' | System | 18 Sep 2020 16:08:41 |
| | System | 18 Sep 2020 16:08:41 |

US3172224

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:33:17

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-18T12:08:36', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'f63622b6-2371-416d-9cb8-6f80238aae68' User entered '18 Sep 2020 12:08' | System | 18 Sep 2020 16:08:41 |
| | System | 18 Sep 2020 16:08:41 |

US3172224

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:33:17

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| User entered '18 Sep 2020 12:00' | System | 16 Sep 2020 19:38:45 |

US3172224

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:33:17

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| User entered '19 Sep 2020 11:59' | System | 16 Sep 2020 19:38:45 |

US3172224

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| Data entry locked. | System | 16 Sep 2020 19:38:45 |
| User entered 'Day 4' | System | 16 Sep 2020 19:38:45 |

US3172224

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:33:17

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-19T16:34:12', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '6bba264f-d7d1-4b33-83bd-acdc76a97d1d' User entered 'None (0)' | System | 19 Sep 2020 20:34:26 |
| | System | 19 Sep 2020 20:34:26 |

US3172224

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:33:17

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-19T16:34:13', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '6bba264f-d7d1-4b33-83bd-acdc76a97d1d' User entered 'None (0)' | System | 19 Sep 2020 20:34:26 |
| | System | 19 Sep 2020 20:34:26 |

US3172224

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:33:17

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-19T16:34:14', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '6bba264f-d7d1-4b33-83bd-acdc76a97d1d' User entered 'None (0)' | System | 19 Sep 2020 20:34:26 |
| | System | 19 Sep 2020 20:34:26 |

US3172224

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:33:17

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-19T16:34:16', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '6bba264f-d7d1-4b33-83bd-acdc76a97d1d' User entered 'None (0)' | System | 19 Sep 2020 20:34:26 |
| | System | 19 Sep 2020 20:34:26 |

US3172224

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:33:17

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-19T16:34:17', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '6bba264f-d7d1-4b33-83bd-acdc76a97d1d' User entered 'None (0)' | System | 19 Sep 2020 20:34:26 |
| | System | 19 Sep 2020 20:34:26 |

US3172224

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:33:17

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-19T16:34:18', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '6bba264f-d7d1-4b33-83bd-acdc76a97d1d' User entered 'None (0)' | System | 19 Sep 2020 20:34:26 |
| | System | 19 Sep 2020 20:34:26 |

US3172224

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-19T16:34:20', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '6bba264f-d7d1-4b33-83bd-acdc76a97d1d' User entered 'No (N)' | System | 19 Sep 2020 20:34:26 |
| | System | 19 Sep 2020 20:34:26 |

US3172224

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:33:17

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-19T16:34:22', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '6bba264f-d7d1-4b33-83bd-acdc76a97d1d' User entered '19 Sep 2020 16:34' | System | 19 Sep 2020 20:34:26 |
| | System | 19 Sep 2020 20:34:26 |

US3172224

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:33:17

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| User entered '19 Sep 2020 12:00' | System | 16 Sep 2020 19:38:45 |

US3172224

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:33:17

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| User entered '20 Sep 2020 11:59' | System | 16 Sep 2020 19:38:45 |

US3172224

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| Data entry locked. | System | 16 Sep 2020 19:38:45 |
| User entered 'Day 5' | System | 16 Sep 2020 19:38:45 |

US3172224

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:33:17

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-20T12:07:14', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '30569391-cd6d-4913-bf3c-33aec5ce05eb' User entered 'None (0)' | System | 20 Sep 2020 16:07:27 |
| | System | 20 Sep 2020 16:07:27 |

US3172224

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:33:17

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-20T12:07:15', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '30569391-cd6d-4913-bf3c-33aec5ce05eb' User entered 'None (0)' | System | 20 Sep 2020 16:07:27 |
| | System | 20 Sep 2020 16:07:27 |

US3172224

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:33:17

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-20T12:07:17', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '30569391-cd6d-4913-bf3c-33aec5ce05eb' User entered 'None (0)' | System | 20 Sep 2020 16:07:27 |
| | System | 20 Sep 2020 16:07:27 |

US3172224

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:33:17

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-20T12:07:18', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '30569391-cd6d-4913-bf3c-33aec5ce05eb' User entered 'None (0)' | System | 20 Sep 2020 16:07:27 |
| | System | 20 Sep 2020 16:07:27 |

US3172224

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:33:17

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-20T12:07:19', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '30569391-cd6d-4913-bf3c-33aec5ce05eb' User entered 'None (0)' | System | 20 Sep 2020 16:07:27 |
| | System | 20 Sep 2020 16:07:27 |

US3172224

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:33:17

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-20T12:07:20', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '30569391-cd6d-4913-bf3c-33aec5ce05eb' User entered 'None (0)' | System | 20 Sep 2020 16:07:27 |
| | System | 20 Sep 2020 16:07:27 |

US3172224

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-20T12:07:21', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '30569391-cd6d-4913-bf3c-33aec5ce05eb' User entered 'No (N)' | System | 20 Sep 2020 16:07:27 |
| | System | 20 Sep 2020 16:07:27 |

US3172224

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:33:17

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-20T12:07:23', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '30569391-cd6d-4913-bf3c-33aec5ce05eb' User entered '20 Sep 2020 12:07' | System | 20 Sep 2020 16:07:27 |
| | System | 20 Sep 2020 16:07:27 |

US3172224

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:33:17

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| User entered '20 Sep 2020 12:00' | System | 16 Sep 2020 19:38:45 |

US3172224

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:33:17

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| User entered '21 Sep 2020 11:59' | System | 16 Sep 2020 19:38:45 |

US3172224

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| Data entry locked. | System | 16 Sep 2020 19:38:45 |
| User entered 'Day 6' | System | 16 Sep 2020 19:38:45 |

US3172224

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:33:17

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-21T12:51:55', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '5244e7ec-55db-46ae-bc27-73c3cfc4e032' User entered 'None (0)' | System | 21 Sep 2020 16:52:08 |
| | System | 21 Sep 2020 16:52:08 |

US3172224

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:33:17

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-21T12:51:56', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '5244e7ec-55db-46ae-bc27-73c3cfc4e032' User entered 'None (0)' | System | 21 Sep 2020 16:52:08 |
| | System | 21 Sep 2020 16:52:08 |

US3172224

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:33:17

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-21T12:51:58', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '5244e7ec-55db-46ae-bc27-73c3cfc4e032' User entered 'None (0)' | System | 21 Sep 2020 16:52:08 |
| | System | 21 Sep 2020 16:52:08 |

US3172224

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:33:17

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-21T12:51:59', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '5244e7ec-55db-46ae-bc27-73c3cfc4e032' User entered 'None (0)' | System | 21 Sep 2020 16:52:08 |
| | System | 21 Sep 2020 16:52:08 |

US3172224

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:33:17

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-21T12:52:00', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '5244e7ec-55db-46ae-bc27-73c3cfc4e032' User entered 'None (0)' | System | 21 Sep 2020 16:52:08 |
| | System | 21 Sep 2020 16:52:08 |

US3172224

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:33:17

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-21T12:52:01', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '5244e7ec-55db-46ae-bc27-73c3cfc4e032' User entered 'None (0)' | System | 21 Sep 2020 16:52:08 |
| | System | 21 Sep 2020 16:52:08 |

US3172224

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-21T12:52:04', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '5244e7ec-55db-46ae-bc27-73c3cfc4e032' | System | 21 Sep 2020 16:52:08 |
| User entered 'No (N)' | System | 21 Sep 2020 16:52:08 |

US3172224

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:33:17

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-21T12:52:06', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '5244e7ec-55db-46ae-bc27-73c3cfc4e032' User entered '21 Sep 2020 12:52' | System | 21 Sep 2020 16:52:08 |
| | System | 21 Sep 2020 16:52:08 |

US3172224

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:33:17

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| User entered '21 Sep 2020 12:00' | System | 16 Sep 2020 19:38:45 |

US3172224

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:33:17

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| User entered '22 Sep 2020 11:59' | System | 16 Sep 2020 19:38:45 |

US3172224

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| Data entry locked. | System | 16 Sep 2020 19:38:45 |
| User entered 'Day 7' | System | 16 Sep 2020 19:38:45 |

US3172224

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:33:17

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-22T15:53:36', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '3eadec9e-c9fd-44fe-ae4c-c84864f7866a' User entered 'None (0)' | System | 22 Sep 2020 19:53:52 |
| | System | 22 Sep 2020 19:53:52 |

US3172224

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:33:17

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-22T15:53:38', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '3eadec9e-c9fd-44fe-ae4c-c84864f7866a' User entered 'None (0)' | System | 22 Sep 2020 19:53:52 |
| | System | 22 Sep 2020 19:53:52 |

US3172224

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:33:17

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-22T15:53:40', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '3eadec9e-c9fd-44fe-ae4c-c84864f7866a' User entered 'None (0)' | System | 22 Sep 2020 19:53:52 |
| | System | 22 Sep 2020 19:53:52 |

US3172224

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:33:17

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-22T15:53:43', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '3eadec9e-c9fd-44fe-ae4c-c84864f7866a' User entered 'None (0)' | System | 22 Sep 2020 19:53:52 |
| | System | 22 Sep 2020 19:53:52 |

US3172224

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:33:17

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-22T15:53:44', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '3eadec9e-c9fd-44fe-ae4c-c84864f7866a' User entered 'None (0)' | System | 22 Sep 2020 19:53:52 |
| | System | 22 Sep 2020 19:53:52 |

US3172224

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:33:17

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-22T15:53:45', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '3eadec9e-c9fd-44fe-ae4c-c84864f7866a' User entered 'None (0)' | System | 22 Sep 2020 19:53:52 |
| | System | 22 Sep 2020 19:53:52 |

US3172224

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-22T15:53:46', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '3eadec9e-c9fd-44fe-ae4c-c84864f7866a' User entered 'No (N)' | System | 22 Sep 2020 19:53:52 |
| | System | 22 Sep 2020 19:53:52 |

US3172224

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:33:17

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-22T15:53:48', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '3eadec9e-c9fd-44fe-ae4c-c84864f7866a' User entered '22 Sep 2020 15:53' | System | 22 Sep 2020 19:53:52 |
| | System | 22 Sep 2020 19:53:52 |

US3172224

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:33:17

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| User entered '22 Sep 2020 12:00' | System | 16 Sep 2020 19:38:45 |

US3172224

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:33:17

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| User entered '23 Sep 2020 11:59' | System | 16 Sep 2020 19:38:45 |

US3172224

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| Data entry locked. | System | 22 Sep 2020 19:53:18 |
| User entered 'Day 8' | System | 22 Sep 2020 19:53:18 |

US3172224

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-23T12:34:18', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '8806011c-5e64-4891-9e98-cdda5ee52144' User entered 'No (N)' | System | 23 Sep 2020 16:34:23 |
| | System | 23 Sep 2020 16:34:23 |

US3172224

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:33:17

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-23T12:34:21', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '8806011c-5e64-4891-9e98-cdda5ee52144' User entered '23 Sep 2020 12:34' | System | 23 Sep 2020 16:34:23 |
| | System | 23 Sep 2020 16:34:23 |

US3172224

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:33:17

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| User entered '23 Sep 2020 12:00' | System | 22 Sep 2020 19:53:18 |

US3172224

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:33:17

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| User entered '24 Sep 2020 11:59' | System | 22 Sep 2020 19:53:18 |

US3172224

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:17

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'Yes (Y)' | Jessie Downs (b) (4) (b) (4) | 24 Sep 2020 16:05:12 |

US3172224

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:17

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered '23 Sep 2020' | Jessie Downs (b) (4) (b) (4) | 24 Sep 2020 16:05:12 |

US3172224

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:17

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'Contact Made (CONTACT MADE)' | Jessie Downs (b) (4) (b) (4) | 24 Sep 2020 16:05:12 |

US3172224

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:17

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered empty. | Jessie Downs (b) (4) (b) (4) | 24 Sep 2020 16:05:12 |

US3172224

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:17

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'Yes (Y)' | Jessie Downs (b) (4) (b) (4) | 24 Sep 2020 16:05:23 |

US3172224

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:17

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User entered 'I' | System | 24 Sep 2020 16:05:23 |

US3172224

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:17

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'Yes (Y)' | Jessie Downs (b) (4) (b) (4) | 01 Oct 2020 13:25:22 |

US3172224

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:17

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered '30 Sep 2020' | Jessie Downs (b) (4) (b) (4) | 01 Oct 2020 13:25:22 |

US3172224

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:17

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'Contact Made (CONTACT MADE)' | Jessie Downs (b) (4) (b) (4) | 01 Oct 2020 13:25:22 |

US3172224

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:17

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered empty. | Jessie Downs (b) (4) (b) (4) | 01 Oct 2020 13:25:22 |

US3172224

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:17

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Jessie Downs (b) (4) (b) (4) | 08 Oct 2020 16:25:27 |
| User entered 'No (N)' reason for change: Data Entry Error | Mariete Rendon (b) (4) (b) (4) | 07 Oct 2020 19:53:42 |
| User entered 'Yes (Y)' | Jessie Downs (b) (4) (b) (4) | 01 Oct 2020 13:25:30 |

US3172224

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:17

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User entered '1' | System | 08 Oct 2020 16:25:27 |
| User entered empty. | System | 07 Oct 2020 19:53:42 |
| User entered '1' | System | 01 Oct 2020 13:25:30 |

US3172224

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:17

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'Yes (Y)' | Jessie Downs (b) (4) (b) (4) | 08 Oct 2020 16:25:39 |

US3172224

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:17

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| User entered '07 Oct 2020' | Jessie Downs (b) (4) | 08 Oct 2020 16:25:39 |
| | (b) (4) | |

US3172224

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:17

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'Contact Made (CONTACT MADE)' | Jessie Downs (b) (4) (b) (4) | 08 Oct 2020 16:25:39 |

US3172224

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:17

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered empty. | Jessie Downs (b) (4) (b) (4) | 08 Oct 2020 16:25:39 |

US3172224

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:17

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Mariete Rendon (b) (4) (b) (4) | 14 Oct 2020 18:49:52 |
| User entered 'No (N)' | Jessie Downs (b) (4) (b) (4) | 08 Oct 2020 16:25:44 |

US3172224

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:17

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User entered '1' | System | 14 Oct 2020 18:49:52 |
| User entered empty. | System | 08 Oct 2020 16:25:44 |

US3172224

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:33:17

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:47 |
| User entered 'Yes (Y)' | Mariete Rendon (b) (4) (b) (4) | 14 Oct 2020 18:50:17 |

US3172224

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:47 |
| User entered '14 Oct 2020' | Mariete Rendon (b) (4) (b) (4) | 14 Oct 2020 18:50:17 |

US3172224

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:47 |
| User entered 'Clinic (Clinic)' | Mariete Rendon (b) (4) (b) (4) | 14 Oct 2020 18:50:17 |

US3172224

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:33:17

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User entered 'VISIT3' | System | 14 Oct 2020 18:50:17 |

US3172224

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:47 |
| User entered 'Yes (Y)' | Mariete Rendon (b) (4) (b) (4) | 14 Oct 2020 18:51:59 |

US3172224

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:47 |
| User entered '14 Oct 2020' | Mariete Rendon (b) (4) (b) (4) | 14 Oct 2020 18:51:59 |

US3172224

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:47 |
| | (b) (4) | |
| User entered '14:19' | Mariete Rendon (b) (4) | 14 Oct 2020 18:51:59 |
| | (b) (4) | |

US3172224

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User entered '14 Oct 2020 14:19' | System | 14 Oct 2020 18:51:59 |

US3172224

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:47 |
| User entered '36.9' C | Mariete Rendon (b) (4) (b) (4) | 14 Oct 2020 18:51:59 |

US3172224

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:47 |
| User entered 'Oral (Oral)' | Mariete Rendon (b) (4) (b) (4) | 14 Oct 2020 18:51:59 |

US3172224

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:47 |
| User entered empty. | Mariete Rendon (b) (4) (b) (4) | 14 Oct 2020 18:51:59 |

US3172224

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:47 |
| User entered '92' | Mariete Rendon (b) (4) (b) (4) | 14 Oct 2020 18:51:59 |

US3172224

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User entered 'bpm' | System | 14 Oct 2020 18:51:59 |

US3172224

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:47 |
| User entered '18' | Mariete Rendon (b) (4) (b) (4) | 14 Oct 2020 18:51:59 |

US3172224

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User entered 'breaths/min' | System | 14 Oct 2020 18:51:59 |

US3172224

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:47 |
| User entered '116' | Mariete Rendon (b) (4) (b) (4) | 14 Oct 2020 18:51:59 |

US3172224

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User entered 'mmHg' | System | 14 Oct 2020 18:51:59 |

US3172224

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:47 |
| User entered '79' | Mariete Rendon (b) (4) (b) (4) | 14 Oct 2020 18:51:59 |

US3172224

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User entered 'mmHg' | System | 14 Oct 2020 18:51:59 |

US3172224

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

Height (derived)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| | | |

US3172224

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

Weight (derived)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| | | |

US3172224

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:33:17

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'No (N)' | Mariete Rendon (b) (4) (b) (4) | 14 Oct 2020 18:52:12 |

US3172224

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:33:17

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered empty. | Mariete Rendon (b) (4) (b) (4) | 14 Oct 2020 18:52:12 |

US3172224

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:33:17

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'Yes (Y)' | Mariete Rendon (b) (4) (b) (4) | 14 Oct 2020 18:52:25 |

US3172224

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:33:17

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered '14 Oct 2020' | Mariete Rendon (b) (4) (b) (4) | 14 Oct 2020 18:52:25 |

US3172224

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:33:17

Collection time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered '14:41' | Mariete Rendon (b) (4) (b) (4) | 14 Oct 2020 18:52:25 |

US3172224

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User entered '14 Oct 2020 14:41' | System | 14 Oct 2020 18:52:25 |

US3172224

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:17

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | (b) (4), (b) (6) | 13 Nov 2020 16:53:52 |
| User entered 'No (N)' | Mariete Rendon (b) (4) (b) (4) | 14 Oct 2020 18:52:28 |

US3172224

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:17

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User entered '1' | System | 13 Nov 2020 16:53:52 |
| User entered empty. | System | 14 Oct 2020 18:52:28 |

US3172224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| Data entry locked. | System | 19 Aug 2020 20:51:16 |
| User entered 'Day 64' | System | 19 Aug 2020 20:51:16 |

US3172224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-10-19T06:07:33', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'f4450daf-250f-4a84-ac89-c10087c0b045' | System | 19 Oct 2020 10:08:03 |
| User entered 'No (N)' | System | 19 Oct 2020 10:08:03 |

US3172224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-10-19T06:07:55', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'f4450daf-250f-4a84-ac89-c10087c0b045' | System | 19 Oct 2020 10:08:03 |
| User entered 'No (N)' | System | 19 Oct 2020 10:08:03 |

US3172224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-10-19T06:07:59', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'f4450daf-250f-4a84-ac89-c10087c0b045' User entered '19 Oct 2020 06:07:59' | System | 19 Oct 2020 10:08:03 |
| | System | 19 Oct 2020 10:08:03 |

US3172224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| Data entry locked. | System | 19 Aug 2020 20:51:16 |
| User entered '19 Oct 2020 00:01' | System | 19 Aug 2020 20:51:16 |

US3172224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| Data entry locked. | System | 19 Aug 2020 20:51:16 |
| User entered '23 Oct 2020 23:59' | System | 19 Aug 2020 20:51:16 |

US3172224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| Data entry locked. | System | 19 Aug 2020 20:51:16 |
| User entered 'Day 71' | System | 19 Aug 2020 20:51:16 |

US3172224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-10-26T05:56:57', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'bc8edf4e-8600-4cb3-93a7-b0d1cbf5a860' User entered 'No (N)' | System | 26 Oct 2020 09:57:20 |
| | System | 26 Oct 2020 09:57:20 |

US3172224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-10-26T05:57:11', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'bc8edf4e-8600-4cb3-93a7-b0d1cbf5a860' | System | 26 Oct 2020 09:57:20 |
| User entered 'No (N)' | System | 26 Oct 2020 09:57:20 |

US3172224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-10-26T05:57:15', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'bc8edf4e-8600-4cb3-93a7-b0d1cbf5a860' User entered '26 Oct 2020 05:57:15' | System | 26 Oct 2020 09:57:20 |
| | System | 26 Oct 2020 09:57:20 |

US3172224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| Data entry locked. | System | 19 Aug 2020 20:51:16 |
| User entered '26 Oct 2020 00:01' | System | 19 Aug 2020 20:51:16 |

US3172224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| Data entry locked. | System | 19 Aug 2020 20:51:16 |
| User entered '30 Oct 2020 23:59' | System | 19 Aug 2020 20:51:16 |

US3172224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| Data entry locked. | System | 19 Aug 2020 20:51:16 |
| User entered 'Day 78' | System | 19 Aug 2020 20:51:16 |

US3172224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-11-02T06:06:07', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '6786e077-6b0e-40bd-ada9-37697e079386' User entered 'No (N)' | System | 02 Nov 2020 11:06:22 |
| | System | 02 Nov 2020 11:06:22 |

US3172224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-11-02T06:06:13', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '6786e077-6b0e-40bd-ada9-37697e079386' | System | 02 Nov 2020 11:06:22 |
| User entered 'No (N)' | System | 02 Nov 2020 11:06:22 |

US3172224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-11-02T06:06:18', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '6786e077-6b0e-40bd-ada9-37697e079386' User entered '02 Nov 2020 06:06:18' | System | 02 Nov 2020 11:06:22 |
| | System | 02 Nov 2020 11:06:22 |

US3172224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| Data entry locked. | System | 19 Aug 2020 20:51:16 |
| User entered '02 Nov 2020 00:01' | System | 19 Aug 2020 20:51:16 |

US3172224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| Data entry locked. | System | 19 Aug 2020 20:51:16 |
| User entered '06 Nov 2020 23:59' | System | 19 Aug 2020 20:51:16 |

US3172224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| Data entry locked. | System | 19 Aug 2020 20:51:16 |
| User entered 'Day 92' | System | 19 Aug 2020 20:51:16 |

US3172224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-11-16T06:20:39', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '9482cf04-7c5d-4086-90d2-f4e932190983' | System | 16 Nov 2020 11:20:52 |
| User entered 'No (N)' | System | 16 Nov 2020 11:20:52 |

US3172224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-11-16T06:20:45', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '9482cf04-7c5d-4086-90d2-f4e932190983' | System | 16 Nov 2020 11:20:52 |
| User entered 'No (N)' | System | 16 Nov 2020 11:20:52 |

US3172224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-11-16T06:20:50', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '9482cf04-7c5d-4086-90d2-f4e932190983' User entered '16 Nov 2020 06:20:50' | System | 16 Nov 2020 11:20:52 |
| | System | 16 Nov 2020 11:20:52 |

US3172224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| Data entry locked. | System | 19 Aug 2020 20:51:16 |
| User entered '16 Nov 2020 00:01' | System | 19 Aug 2020 20:51:16 |

US3172224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 19:57:11 |
| Data entry locked. | System | 19 Aug 2020 20:51:16 |
| User entered '20 Nov 2020 23:59' | System | 19 Aug 2020 20:51:16 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered 'Day 96' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-11-23T06:03:30', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '78ae8d18-cc53-4615-8af0-dc773faa50a1' User entered 'No (N)' | System | 23 Nov 2020 11:03:51 |
| | System | 23 Nov 2020 11:03:51 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

Have you been exposed to someone with 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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-11-23T06:03:45', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '78ae8d18-cc53-4615-8af0-dc773faa50a1' User entered 'No (N)' | System | 23 Nov 2020 11:03:51 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-11-23T06:03:48', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '78ae8d18-cc53-4615-8af0-dc773faa50a1' User entered '23 Nov 2020 06:03:48' | System | 23 Nov 2020 11:03:51 |
| | System | 23 Nov 2020 11:03:51 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '20 Nov 2020 00:01' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '24 Nov 2020 23:59' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered 'Day 103' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-11-27T01:37:14', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '9844db26-1b7c-469a-b8d5-e568217b98ee' User entered 'No (N)' | System | 27 Nov 2020 06:37:29 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

Have you been exposed to someone with 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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-11-27T01:37:25', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '9844db26-1b7c-469a-b8d5-e568217b98ee' User entered 'No (N)' | System | 27 Nov 2020 06:37:29 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-11-27T01:37:28', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '9844db26-1b7c-469a-b8d5-e568217b98ee' User entered '27 Nov 2020 01:37:28' | System | 27 Nov 2020 06:37:29 |
| | System | 27 Nov 2020 06:37:29 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '27 Nov 2020 00:01' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '01 Dec 2020 23:59' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered 'Day 110' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-12-05T07:56:55', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'b06e3ec3-2f8f-433e-9f94-633b04198b10' | System | 05 Dec 2020 12:57:04 |
| User entered 'No (N)' | System | 05 Dec 2020 12:57:04 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

Have you been exposed to someone with 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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-12-05T07:56:56', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'b06e3ec3-2f8f-433e-9f94-633b04198b10' | System | 05 Dec 2020 12:57:04 |
| User entered 'No (N)' | System | 05 Dec 2020 12:57:04 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-12-05T07:56:59', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'b06e3ec3-2f8f-433e-9f94-633b04198b10' User entered '05 Dec 2020 07:56:59' | System | 05 Dec 2020 12:57:04 |
| | System | 05 Dec 2020 12:57:04 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '04 Dec 2020 00:01' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '08 Dec 2020 23:59' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered 'Day 117' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-12-11T05:55:52', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '8edfb976-c674-4ced-b6ff-4d325a272a5d' User entered 'No (N)' | System | 11 Dec 2020 10:56:03 |
| | System | 11 Dec 2020 10:56:03 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

Have you been exposed to someone with 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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-12-11T05:55:56', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '8edfb976-c674-4ced-b6ff-4d325a272a5d' User entered 'No (N)' | System | 11 Dec 2020 10:56:03 |
| | System | 11 Dec 2020 10:56:03 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-12-11T05:55:59', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '8edfb976-c674-4ced-b6ff-4d325a272a5d' User entered '11 Dec 2020 05:55:59' | System | 11 Dec 2020 10:56:03 |
| | System | 11 Dec 2020 10:56:03 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '11 Dec 2020 00:01' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '15 Dec 2020 23:59' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered 'Day 124' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-12-18T05:52:51', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'c4dee4c4-f707-44d7-b86a-26cf8e18c23a' User entered 'No (N)' | System | 18 Dec 2020 10:53:00 |
| | System | 18 Dec 2020 10:53:00 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Have you been exposed to someone with 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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-12-18T05:52:53', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'c4dee4c4-f707-44d7-b86a-26cf8e18c23a' User entered 'No (N)' | System | 18 Dec 2020 10:53:00 |
| | System | 18 Dec 2020 10:53:00 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-12-18T05:52:57', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'c4dee4c4-f707-44d7-b86a-26cf8e18c23a' User entered '18 Dec 2020 05:52:57' | System | 18 Dec 2020 10:53:00 |
| | System | 18 Dec 2020 10:53:00 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '18 Dec 2020 00:01' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '22 Dec 2020 23:59' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered 'Day 131' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-12-25T08:59:25', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '950c01cd-bda5-43ca-84fa-00624824247c' User entered 'No (N)' | System | 25 Dec 2020 13:59:41 |
| | System | 25 Dec 2020 13:59:41 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Have you been exposed to someone with 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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-12-25T08:59:37', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '950c01cd-bda5-43ca-84fa-00624824247c' User entered 'No (N)' | System | 25 Dec 2020 13:59:41 |
| | System | 25 Dec 2020 13:59:41 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-12-25T08:59:40', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '950c01cd-bda5-43ca-84fa-00624824247c' User entered '25 Dec 2020 08:59:40' | System | 25 Dec 2020 13:59:41 |
| | System | 25 Dec 2020 13:59:41 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '25 Dec 2020 00:01' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '29 Dec 2020 23:59' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered 'Day 138' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-01-01T00:15:20', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'b6e68d1e-b3da-482b-892c-29e9c0c23d67' | System | 01 Jan 2021 05:15:31 |
| User entered 'No (N)' | System | 01 Jan 2021 05:15:31 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

Have you been exposed to someone with 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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-01-01T00:15:23', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'b6e68d1e-b3da-482b-892c-29e9c0c23d67' | System | 01 Jan 2021 05:15:31 |
| User entered 'No (N)' | System | 01 Jan 2021 05:15:31 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-01-01T00:15:29', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'b6e68d1e-b3da-482b-892c-29e9c0c23d67' User entered '01 Jan 2021 00:15:29' | System | 01 Jan 2021 05:15:31 |
| | System | 01 Jan 2021 05:15:31 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '01 Jan 2021 00:01' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '05 Jan 2021 23:59' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered 'Day 145' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-01-08T05:52:53', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '418bea1f-428b-4c6a-b91f-88fc6e541a3c' | System | 08 Jan 2021 10:53:58 |
| User entered 'No (N)' | System | 08 Jan 2021 10:53:58 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

Have you been exposed to someone with 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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-01-08T05:53:26', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '418bea1f-428b-4c6a-b91f-88fc6e541a3c' User entered 'Yes (Y)' | System | 08 Jan 2021 10:53:58 |
| | System | 08 Jan 2021 10:53:58 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

Please 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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-01-08T05:53:43', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '418bea1f-428b-4c6a-b91f-88fc6e541a3c' | System | 08 Jan 2021 10:53:58 |
| User entered 'I confirm I have read this message and will call the study clinic immediately (9)' | System | 08 Jan 2021 10:53:58 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-01-08T05:53:48', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '418bea1f-428b-4c6a-b91f-88fc6e541a3c' User entered '08 Jan 2021 05:53:48' | System | 08 Jan 2021 10:53:58 |
| | System | 08 Jan 2021 10:53:58 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '08 Jan 2021 00:01' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '12 Jan 2021 23:59' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered 'Day 152' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-01-15T06:07:26', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '79e47fd3-142f-4981-a807-c570bc0a968b' User entered 'No (N)' | System | 15 Jan 2021 11:07:38 |
| | System | 15 Jan 2021 11:07:38 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

Have you been exposed to someone with 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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-01-15T06:07:32', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '79e47fd3-142f-4981-a807-c570bc0a968b' User entered 'No (N)' | System | 15 Jan 2021 11:07:38 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-01-15T06:07:35', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '79e47fd3-142f-4981-a807-c570bc0a968b' User entered '15 Jan 2021 06:07:35' | System | 15 Jan 2021 11:07:38 |
| | System | 15 Jan 2021 11:07:38 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '15 Jan 2021 00:01' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '19 Jan 2021 23:59' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered 'Day 159' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-01-22T05:53:07', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '7a2a94cb-6309-46b1-af05-3effa8dc683a' User entered 'Yes (Y)' | System | 22 Jan 2021 10:53:44 |
| | System | 22 Jan 2021 10:53:44 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

Have you been exposed to someone with 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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-01-22T05:53:14', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '7a2a94cb-6309-46b1-af05-3effa8dc683a' User entered 'No (N)' | System | 22 Jan 2021 10:53:44 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-01-22T05:53:24', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '7a2a94cb-6309-46b1-af05-3effa8dc683a' User entered 'No (N)' | System | 22 Jan 2021 10:53:44 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-01-22T05:53:34', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '7a2a94cb-6309-46b1-af05-3effa8dc683a' User entered 'No (N)' | System | 22 Jan 2021 10:53:44 |
| | System | 22 Jan 2021 10:53:44 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-01-22T05:53:41', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '7a2a94cb-6309-46b1-af05-3effa8dc683a' User entered '22 Jan 2021 05:53:41' | System | 22 Jan 2021 10:53:44 |
| | System | 22 Jan 2021 10:53:44 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '22 Jan 2021 00:01' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '26 Jan 2021 23:59' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered 'Day 166' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-01-29T09:23:57', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '8cdc97c8-d274-49a9-b7ca-6b4b626e7850' User entered 'Yes (Y)' | System | 29 Jan 2021 14:24:31 |
| | System | 29 Jan 2021 14:24:31 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

Have you been exposed to someone with 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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-01-29T09:24:01', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '8cdc97c8-d274-49a9-b7ca-6b4b626e7850' | System | 29 Jan 2021 14:24:31 |
| User entered 'No (N)' | System | 29 Jan 2021 14:24:31 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-01-29T09:24:05', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '8cdc97c8-d274-49a9-b7ca-6b4b626e7850' User entered 'No (N)' | System | 29 Jan 2021 14:24:31 |
| | System | 29 Jan 2021 14:24:31 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-01-29T09:24:12', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '8cdc97c8-d274-49a9-b7ca-6b4b626e7850' User entered 'Yes (Y)' | System | 29 Jan 2021 14:24:31 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Please 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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-01-29T09:24:16', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '8cdc97c8-d274-49a9-b7ca-6b4b626e7850' | System | 29 Jan 2021 14:24:31 |
| User entered 'I confirm I have read this message and will call the study clinic immediately (9)' | System | 29 Jan 2021 14:24:31 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-01-29T09:24:20', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '8cdc97c8-d274-49a9-b7ca-6b4b626e7850' User entered '29 Jan 2021 09:24:20' | System | 29 Jan 2021 14:24:31 |
| | System | 29 Jan 2021 14:24:31 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '29 Jan 2021 00:01' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '02 Feb 2021 23:59' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered 'Day 173' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-02-05T06:30:46', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '6302b9c7-3cae-4097-94de-ec543f94628d' User entered 'No (N)' | System | 05 Feb 2021 11:30:56 |
| | System | 05 Feb 2021 11:30:56 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

Have you been exposed to someone with 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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-02-05T06:30:49', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '6302b9c7-3cae-4097-94de-ec543f94628d' User entered 'No (N)' | System | 05 Feb 2021 11:30:56 |
| | System | 05 Feb 2021 11:30:56 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-02-05T06:30:53', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '6302b9c7-3cae-4097-94de-ec543f94628d' User entered '05 Feb 2021 06:30:53' | System | 05 Feb 2021 11:30:56 |
| | System | 05 Feb 2021 11:30:56 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '05 Feb 2021 00:01' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '09 Feb 2021 23:59' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered 'Day 180' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-02-12T06:41:06', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'fc111e71-8666-4ab9-bd38-4dd3805aabf1' User entered 'No (N)' | System | 12 Feb 2021 11:41:17 |
| | System | 12 Feb 2021 11:41:17 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

Have you been exposed to someone with 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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-02-12T06:41:10', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'fc111e71-8666-4ab9-bd38-4dd3805aabf1' User entered 'No (N)' | System | 12 Feb 2021 11:41:17 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-02-12T06:41:15', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'fc111e71-8666-4ab9-bd38-4dd3805aabf1' User entered '12 Feb 2021 06:41:15' | System | 12 Feb 2021 11:41:17 |
| | System | 12 Feb 2021 11:41:17 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '12 Feb 2021 00:01' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '16 Feb 2021 23:59' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered 'Day 187' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-02-21T12:00:19', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'e980b008-16a1-42c5-97dc-74e562030943' | System | 21 Feb 2021 17:01:28 |
| User entered 'No (N)' | System | 21 Feb 2021 17:01:28 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

Have you been exposed to someone with 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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-02-21T12:00:22', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'e980b008-16a1-42c5-97dc-74e562030943' | System | 21 Feb 2021 17:01:28 |
| User entered 'No (N)' | System | 21 Feb 2021 17:01:28 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-02-21T12:00:25', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'e980b008-16a1-42c5-97dc-74e562030943' | System | 21 Feb 2021 17:01:28 |
| User entered '21 Feb 2021 12:00:25' | System | 21 Feb 2021 17:01:28 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '19 Feb 2021 00:01' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '23 Feb 2021 23:59' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered 'Day 194' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-02-26T00:30:14-05:00', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '9b0c40ba-e76a-4214-aa6b-9cb12057069c' User entered 'No (N)' | System | 26 Feb 2021 05:30:24 |
| | System | 26 Feb 2021 05:30:24 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

Have you been exposed to someone with 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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-02-26T00:30:18-05:00', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '9b0c40ba-e76a-4214-aa6b-9cb12057069c' User entered 'No (N)' | System | 26 Feb 2021 05:30:24 |
| | System | 26 Feb 2021 05:30:24 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-02-26T00:30:22-05:00', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '9b0c40ba-e76a-4214-aa6b-9cb12057069c' User entered '26 Feb 2021 05:30:22' | System | 26 Feb 2021 05:30:24 |
| | System | 26 Feb 2021 05:30:24 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '26 Feb 2021 00:01' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '02 Mar 2021 23:59' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered 'Day 201' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-03-05T06:07:34-05:00', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '62017058-08ed-42a2-b784-4fcd4cb22194' | System | 05 Mar 2021 11:07:44 |
| User entered 'No (N)' | System | 05 Mar 2021 11:07:44 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

Have you been exposed to someone with 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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-03-05T06:07:38-05:00', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '62017058-08ed-42a2-b784-4fcd4cb22194' | System | 05 Mar 2021 11:07:44 |
| User entered 'No (N)' | System | 05 Mar 2021 11:07:44 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-03-05T06:07:40-05:00', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '62017058-08ed-42a2-b784-4fcd4cb22194' User entered '05 Mar 2021 06:07:40' | System | 05 Mar 2021 11:07:44 |
| | System | 05 Mar 2021 11:07:44 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '05 Mar 2021 00:01' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '09 Mar 2021 23:59' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered 'Day 208' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-03-12T05:45:40-05:00', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '1eeda4f3-7f6c-4db8-b141-b8519af1ebc7' | System | 12 Mar 2021 10:45:50 |
| User entered 'No (N)' | System | 12 Mar 2021 10:45:50 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Have you been exposed to someone with 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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-03-12T05:45:43-05:00', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '1eeda4f3-7f6c-4db8-b141-b8519af1ebc7' | System | 12 Mar 2021 10:45:50 |
| User entered 'No (N)' | System | 12 Mar 2021 10:45:50 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-03-12T05:45:46-05:00', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '1eeda4f3-7f6c-4db8-b141-b8519af1ebc7' User entered '12 Mar 2021 05:45:46' | System | 12 Mar 2021 10:45:50 |
| | System | 12 Mar 2021 10:45:50 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '12 Mar 2021 00:01' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '16 Mar 2021 23:59' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered 'Day 215' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-03-19T05:28:06-04:00', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '6083ca33-98ba-4e2c-b7fc-e131b0b71da6' | System | 19 Mar 2021 09:28:14 |
| User entered 'No (N)' | System | 19 Mar 2021 09:28:14 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

Have you been exposed to someone with 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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-03-19T05:28:10-04:00', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '6083ca33-98ba-4e2c-b7fc-e131b0b71da6' | System | 19 Mar 2021 09:28:14 |
| User entered 'No (N)' | System | 19 Mar 2021 09:28:14 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-03-19T05:28:12-04:00', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '6083ca33-98ba-4e2c-b7fc-e131b0b71da6' | System | 19 Mar 2021 09:28:14 |
| User entered '19 Mar 2021 05:28:12' | System | 19 Mar 2021 09:28:14 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '19 Mar 2021 00:01' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '23 Mar 2021 23:59' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered 'Day 222' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-03-26T06:39:39-04:00', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '0903a66f-6d70-4fa4-8934-8b7f5788407b' User entered 'No (N)' | System | 26 Mar 2021 10:39:51 |
| | System | 26 Mar 2021 10:39:51 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

Have you been exposed to someone with 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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-03-26T06:39:42-04:00', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '0903a66f-6d70-4fa4-8934-8b7f5788407b' User entered 'No (N)' | System | 26 Mar 2021 10:39:51 |
| | System | 26 Mar 2021 10:39:51 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-03-26T06:39:49-04:00', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '0903a66f-6d70-4fa4-8934-8b7f5788407b' User entered '26 Mar 2021 06:39:49' | System | 26 Mar 2021 10:39:51 |
| | System | 26 Mar 2021 10:39:51 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '26 Mar 2021 00:01' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '30 Mar 2021 23:59' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered 'Day 229' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-04-02T06:28:23-04:00', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '246da140-cc5b-413d-9a5c-b0ac5b3e919b' User entered 'No (N)' | System | 02 Apr 2021 10:28:36 |
| | System | 02 Apr 2021 10:28:36 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

Have you been exposed to someone with 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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-04-02T06:28:27-04:00', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '246da140-cc5b-413d-9a5c-b0ac5b3e919b' User entered 'No (N)' | System | 02 Apr 2021 10:28:36 |
| | System | 02 Apr 2021 10:28:36 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-04-02T06:28:30-04:00', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '246da140-cc5b-413d-9a5c-b0ac5b3e919b' | System | 02 Apr 2021 10:28:36 |
| User entered '02 Apr 2021 06:28:30' | System | 02 Apr 2021 10:28:36 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '02 Apr 2021 00:01' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '06 Apr 2021 23:59' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered 'Day 236' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-04-09T06:08:47-04:00', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'c2479a83-4a67-4c33-bed9-8c36ead32c15' | System | 09 Apr 2021 10:08:54 |
| User entered 'No (N)' | System | 09 Apr 2021 10:08:54 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

Have you been exposed to someone with 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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-04-09T06:08:49-04:00', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'c2479a83-4a67-4c33-bed9-8c36ead32c15' | System | 09 Apr 2021 10:08:54 |
| User entered 'No (N)' | System | 09 Apr 2021 10:08:54 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-04-09T06:08:51-04:00', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'c2479a83-4a67-4c33-bed9-8c36ead32c15' | System | 09 Apr 2021 10:08:54 |
| User entered '09 Apr 2021 06:08:51' | System | 09 Apr 2021 10:08:54 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '09 Apr 2021 00:01' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '13 Apr 2021 23:59' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered 'Day 243' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-04-16T06:02:52-04:00', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '7440e976-0c52-48ee-a197-dc98621949e0' User entered 'No (N)' | System | 16 Apr 2021 10:03:02 |
| | System | 16 Apr 2021 10:03:02 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

Have you been exposed to someone with 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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-04-16T06:02:55-04:00', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '7440e976-0c52-48ee-a197-dc98621949e0' User entered 'No (N)' | System | 16 Apr 2021 10:03:02 |
| | System | 16 Apr 2021 10:03:02 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-04-16T06:02:59-04:00', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '7440e976-0c52-48ee-a197-dc98621949e0' User entered '16 Apr 2021 06:02:59' | System | 16 Apr 2021 10:03:02 |
| | System | 16 Apr 2021 10:03:02 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '16 Apr 2021 00:01' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '20 Apr 2021 23:59' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered 'Day 250' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-04-23T06:06:29-04:00', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'f8c29dd4-f18c-4b90-92c9-b5c5c73ab32f' User entered 'No (N)' | System | 23 Apr 2021 10:06:37 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

Have you been exposed to someone with 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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-04-23T06:06:32-04:00', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'f8c29dd4-f18c-4b90-92c9-b5c5c73ab32f' User entered 'No (N)' | System | 23 Apr 2021 10:06:37 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-04-23T06:06:34-04:00', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'f8c29dd4-f18c-4b90-92c9-b5c5c73ab32f' User entered '23 Apr 2021 06:06:34' | System | 23 Apr 2021 10:06:37 |
| | System | 23 Apr 2021 10:06:37 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '23 Apr 2021 00:01' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '27 Apr 2021 23:59' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered 'Day 257' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-04-30T06:11:28-04:00', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'feab3c17-316d-44ce-bd56-693c20083764' | System | 30 Apr 2021 10:11:36 |
| User entered 'No (N)' | System | 30 Apr 2021 10:11:36 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

Have you been exposed to someone with 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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-04-30T06:11:30-04:00', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'feab3c17-316d-44ce-bd56-693c20083764' User entered 'No (N)' | System | 30 Apr 2021 10:11:36 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-04-30T06:11:33-04:00', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'feab3c17-316d-44ce-bd56-693c20083764' User entered '30 Apr 2021 06:11:33' | System | 30 Apr 2021 10:11:36 |
| | System | 30 Apr 2021 10:11:36 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '30 Apr 2021 00:01' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '04 May 2021 23:59' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered 'Day 264' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '07 May 2021 00:01' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '11 May 2021 23:59' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered 'Day 271' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '14 May 2021 00:01' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '18 May 2021 23:59' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered 'Day 278' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '21 May 2021 00:01' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '25 May 2021 23:59' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered 'Day 285' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '28 May 2021 00:01' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '01 Jun 2021 23:59' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered 'Day 292' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '04 Jun 2021 00:01' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '08 Jun 2021 23:59' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered 'Day 299' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '11 Jun 2021 00:01' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '15 Jun 2021 23:59' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered 'Day 306' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '18 Jun 2021 00:01' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '22 Jun 2021 23:59' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered 'Day 313' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '25 Jun 2021 00:01' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '29 Jun 2021 23:59' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered 'Day 320' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '02 Jul 2021 00:01' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '06 Jul 2021 23:59' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered 'Day 327' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '09 Jul 2021 00:01' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '13 Jul 2021 23:59' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered 'Day 334' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '16 Jul 2021 00:01' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '20 Jul 2021 23:59' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered 'Day 341' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '23 Jul 2021 00:01' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '27 Jul 2021 23:59' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered 'Day 348' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '30 Jul 2021 00:01' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '03 Aug 2021 23:59' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered 'Day 355' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '06 Aug 2021 00:01' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '10 Aug 2021 23:59' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered 'Day 362' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '13 Aug 2021 00:01' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '17 Aug 2021 23:59' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered 'Day 369' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '20 Aug 2021 00:01' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '24 Aug 2021 23:59' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered 'Day 376' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '27 Aug 2021 00:01' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '31 Aug 2021 23:59' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered 'Day 383' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '03 Sep 2021 00:01' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '07 Sep 2021 23:59' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered 'Day 390' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '10 Sep 2021 00:01' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '14 Sep 2021 23:59' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered 'Day 397' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '17 Sep 2021 00:01' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '21 Sep 2021 23:59' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered 'Day 404' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '24 Sep 2021 00:01' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '28 Sep 2021 23:59' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered 'Day 411' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '01 Oct 2021 00:01' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '05 Oct 2021 23:59' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered 'Day 418' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '08 Oct 2021 00:01' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '12 Oct 2021 23:59' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered 'Day 425' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '15 Oct 2021 00:01' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '19 Oct 2021 23:59' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered 'Day 432' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '22 Oct 2021 00:01' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '26 Oct 2021 23:59' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered 'Day 439' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '29 Oct 2021 00:01' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '02 Nov 2021 23:59' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered 'Day 446' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '05 Nov 2021 00:01' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '09 Nov 2021 23:59' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered 'Day 453' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '12 Nov 2021 00:01' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '16 Nov 2021 23:59' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered 'Day 460' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '19 Nov 2021 00:01' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '23 Nov 2021 23:59' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered 'Day 467' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '26 Nov 2021 00:01' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '30 Nov 2021 23:59' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered 'Day 474' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '03 Dec 2021 00:01' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '07 Dec 2021 23:59' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered 'Day 481' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '10 Dec 2021 00:01' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '14 Dec 2021 23:59' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered 'Day 488' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '17 Dec 2021 00:01' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '21 Dec 2021 23:59' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered 'Day 495' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '24 Dec 2021 00:01' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '28 Dec 2021 23:59' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered 'Day 502' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '31 Dec 2021 00:01' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '04 Jan 2022 23:59' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered 'Day 509' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '07 Jan 2022 00:01' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '11 Jan 2022 23:59' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered 'Day 516' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '14 Jan 2022 00:01' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '18 Jan 2022 23:59' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered 'Day 523' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '21 Jan 2022 00:01' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '25 Jan 2022 23:59' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered 'Day 530' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '28 Jan 2022 00:01' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '01 Feb 2022 23:59' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered 'Day 537' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '04 Feb 2022 00:01' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '08 Feb 2022 23:59' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered 'Day 544' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '11 Feb 2022 00:01' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '15 Feb 2022 23:59' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered 'Day 551' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '18 Feb 2022 00:01' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '22 Feb 2022 23:59' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered 'Day 558' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '25 Feb 2022 00:01' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '01 Mar 2022 23:59' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered 'Day 565' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '04 Mar 2022 00:01' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '08 Mar 2022 23:59' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered 'Day 572' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '11 Mar 2022 00:01' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '15 Mar 2022 23:59' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered 'Day 579' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '18 Mar 2022 00:01' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '22 Mar 2022 23:59' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered 'Day 586' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '25 Mar 2022 00:01' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '29 Mar 2022 23:59' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered 'Day 593' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '01 Apr 2022 00:01' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '05 Apr 2022 23:59' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered 'Day 600' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '08 Apr 2022 00:01' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '12 Apr 2022 23:59' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered 'Day 607' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '15 Apr 2022 00:01' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '19 Apr 2022 23:59' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered 'Day 614' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '22 Apr 2022 00:01' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '26 Apr 2022 23:59' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered 'Day 621' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '29 Apr 2022 00:01' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '03 May 2022 23:59' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered 'Day 628' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '06 May 2022 00:01' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '10 May 2022 23:59' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered 'Day 635' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '13 May 2022 00:01' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '17 May 2022 23:59' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered 'Day 642' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '20 May 2022 00:01' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '24 May 2022 23:59' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered 'Day 649' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '27 May 2022 00:01' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '31 May 2022 23:59' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered 'Day 656' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '03 Jun 2022 00:01' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '07 Jun 2022 23:59' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered 'Day 663' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '10 Jun 2022 00:01' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '14 Jun 2022 23:59' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered 'Day 670' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '17 Jun 2022 00:01' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '21 Jun 2022 23:59' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered 'Day 677' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '24 Jun 2022 00:01' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '28 Jun 2022 23:59' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered 'Day 684' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '01 Jul 2022 00:01' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '05 Jul 2022 23:59' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered 'Day 691' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '08 Jul 2022 00:01' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '12 Jul 2022 23:59' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered 'Day 698' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '15 Jul 2022 00:01' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '19 Jul 2022 23:59' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered 'Day 705' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '22 Jul 2022 00:01' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '26 Jul 2022 23:59' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered 'Day 712' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

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| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '29 Jul 2022 00:01' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '02 Aug 2022 23:59' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered 'Day 719' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '05 Aug 2022 00:01' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '09 Aug 2022 23:59' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered 'Day 726' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '12 Aug 2022 00:01' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '16 Aug 2022 23:59' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered 'Day 733' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '19 Aug 2022 00:01' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '23 Aug 2022 23:59' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered 'Day 740' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '26 Aug 2022 00:01' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '30 Aug 2022 23:59' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered 'Day 747' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '02 Sep 2022 00:01' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '06 Sep 2022 23:59' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered 'Day 754' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '09 Sep 2022 00:01' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '13 Sep 2022 23:59' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered 'Day 761' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '16 Sep 2022 00:01' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '20 Sep 2022 23:59' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered 'Day 768' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '23 Sep 2022 00:01' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '27 Sep 2022 23:59' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered 'Day 775' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '30 Sep 2022 00:01' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '04 Oct 2022 23:59' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered 'Day 782' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '07 Oct 2022 00:01' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '11 Oct 2022 23:59' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered 'Day 789' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '14 Oct 2022 00:01' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '18 Oct 2022 23:59' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered 'Day 796' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '21 Oct 2022 00:01' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:15:15 |
| Amendment Manager: User entered '25 Oct 2022 23:59' | System | 19 Nov 2020 23:15:15 |

US3172224

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:33:17

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 21:49:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-03-05T06:07:47-05:00', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '5e24828d-2a54-431c-aac5-feb117c1cf1e' | System | 05 Mar 2021 11:07:56 |
| User entered 'No (N)' | System | 05 Mar 2021 11:07:56 |

US3172224

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:33:17

[Date & Time of Submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 21:49:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-03-05T06:07:50-05:00', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '5e24828d-2a54-431c-aac5-feb117c1cf1e' User entered '05 Mar 2021 06:07:50' | System | 05 Mar 2021 11:07:56 |
| | System | 05 Mar 2021 11:07:56 |

US3172224

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:17

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 13 Nov 2020 16:54:50 |

US3172224

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:17

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered '12 Nov 2020' | (b) (4), (b) (6) | 13 Nov 2020 16:54:50 |

US3172224

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:17

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4), (b) (6) | 13 Nov 2020 16:54:50 |

US3172224

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:17

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered empty. | (b) (4), (b) (6) | 13 Nov 2020 16:54:50 |

US3172224

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:17

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 13 Nov 2020 16:54:55 |

US3172224

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:17

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 07:11:34 |
| User entered 'I' | System | 13 Nov 2020 16:54:55 |

US3172224

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:17

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 16 Apr 2021 14:01:21 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'Yes (Y)' | Jessie Downs (b) (4) (b) (4) | 15 Dec 2020 20:00:40 |

US3172224

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:17

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 16 Apr 2021 14:01:21 |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| User entered '15 Dec 2020' | Jessie Downs (b) (4) | 15 Dec 2020 20:00:40 |
| | (b) (4) | |

US3172224

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:17

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 16 Apr 2021 14:01:21 |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| User entered 'Contact Made (CONTACT MADE)' | Jessie Downs (b) (4) | 15 Dec 2020 20:00:40 |
| | (b) (4) | |

US3172224

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:17

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 16 Apr 2021 14:01:21 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered empty. | Jessie Downs (b) (4) (b) (4) | 15 Dec 2020 20:00:40 |

US3172224

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:17

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 16 Apr 2021 14:01:21 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'Yes (Y)' | Jessie Downs (b) (4) (b) (4) | 15 Dec 2020 20:00:54 |

US3172224

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:17

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 16 Apr 2021 14:01:21 |
| User entered 'I' | System | 15 Dec 2020 20:00:54 |

US3172224

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:17

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 16 Apr 2021 14:01:21 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'Yes (Y)' | Jessie Downs (b) (4) (b) (4) | 20 Jan 2021 14:48:20 |

US3172224

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:17

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 16 Apr 2021 14:01:21 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User closed query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 29JAN2021 under Participant Decision Visit / OL-D1 in PPD central lab, however same is missing in EDC. Please reconcile the data and update as appropriate. Else clarify, thank you.' (Site from DM). | (b) (4), (b) (6) | 11 Feb 2021 07:33:31 |
| Query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 29JAN2021 under Participant Decision Visit / OL-D1 in PPD central lab, however same is missing in EDC. Please reconcile the data and update as appropriate. Else clarify, thank you.' answered with 'Data was updated ' (Site from DM). | Jessie Downs (b) (4) (b) (4) | 06 Feb 2021 19:38:06 |
| User opened query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 29JAN2021 under Participant Decision Visit / OL-D1 in PPD central lab, however same is missing in EDC. Please reconcile the data and update as appropriate. Else clarify, thank you.' (Site from DM). | (b) (4), (b) (6) | 04 Feb 2021 09:53:43 |
| User closed query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System). | (b) (4), (b) (6) | 22 Jan 2021 05:17:40 |
| Query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' answered with 'Date confirmed as entered.' (Site from System). | Jessie Downs (b) (4) (b) (4) | 20 Jan 2021 14:48:42 |
| User opened query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System). | System | 20 Jan 2021 14:48:20 |
| User entered '18 Jan 2021' | Jessie Downs (b) (4) (b) (4) | 20 Jan 2021 14:48:20 |

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3172224

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:17

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 16 Apr 2021 14:01:21 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'Contact Made (CONTACT MADE)' | Jessie Downs (b) (4) (b) (4) | 20 Jan 2021 14:48:20 |

US3172224

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:17

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 16 Apr 2021 14:01:21 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered empty. | Jessie Downs (b) (4) (b) (4) | 20 Jan 2021 14:48:20 |

US3172224

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:17

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 16 Apr 2021 14:01:21 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'Yes (Y)' | Jessie Downs (b) (4) (b) (4) | 20 Jan 2021 14:48:52 |

US3172224

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:17

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 16 Apr 2021 14:01:21 |
| User entered 'I' | System | 20 Jan 2021 14:48:52 |

US3172224

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:17

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 16 Apr 2021 14:01:21 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'Yes (Y)' | Jessie Downs (b) (4) (b) (4) | 15 Feb 2021 21:48:55 |

US3172224

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:17

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 16 Apr 2021 14:01:21 |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| User entered '15 Feb 2021' | Jessie Downs (b) (4) | 15 Feb 2021 21:48:55 |
| | (b) (4) | |

US3172224

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:17

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 16 Apr 2021 14:01:21 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'Contact Made (CONTACT MADE)' | Jessie Downs (b) (4) (b) (4) | 15 Feb 2021 21:48:55 |

US3172224

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:17

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 16 Apr 2021 14:01:21 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered empty. | Jessie Downs (b) (4) (b) (4) | 15 Feb 2021 21:48:55 |

US3172224

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:17

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 16 Apr 2021 14:01:21 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'Yes (Y)' | Jessie Downs (b) (4) (b) (4) | 15 Feb 2021 21:49:07 |

US3172224

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:17

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 16 Apr 2021 14:01:21 |
| User entered '1' | System | 15 Feb 2021 21:49:07 |

US3172224

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:33:17

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) | 22 Apr 2021 16:25:33 |
| | (b) (4) | |
| User entered 'No (N)' reason for change: Data Entry Error | Jessie Downs (b) (4) | 01 Apr 2021 20:12:05 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4) | |
| Query 'Data is required. Please complete.' answered with 'Data added in error' (Site from System). | (b) (4), (b) (6) | 31 Mar 2021 06:48:42 |
| User opened query 'Data is required. Please complete.' (Site from System). | Jessie Downs (b) (4) | 26 Mar 2021 19:58:17 |
| User entered empty; reason for change Data Entry Error | (b) (4) | |
| User entered 'Yes (Y)' | System | 26 Mar 2021 19:57:59 |
| | Jessie Downs (b) (4) | 26 Mar 2021 19:57:59 |
| | (b) (4) | |
| | Jessie Downs (b) (4) | 26 Mar 2021 19:46:15 |
| | (b) (4) | |

US3172224

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) | 22 Apr 2021 16:25:33 |
| | (b) (4) | |
| User entered empty; reason for change Data Entry Error | Jessie Downs (b) (4) | 26 Mar 2021 19:57:59 |
| | (b) (4) | |
| User entered '19 Mar 2021' | Jessie Downs (b) (4) | 26 Mar 2021 19:46:15 |
| | (b) (4) | |

US3172224

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) | 22 Apr 2021 16:25:33 |
| | (b) (4) | |
| User entered empty; reason for change Data Entry Error | Jessie Downs (b) (4) | 26 Mar 2021 19:57:59 |
| | (b) (4) | |
| User entered 'Clinic (Clinic)' | Jessie Downs (b) (4) | 26 Mar 2021 19:46:15 |
| | (b) (4) | |

US3172224

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:33:17

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|--------|----------------------|
| User entered 'VISIT4' | System | 01 Apr 2021 20:12:05 |
| User entered empty. | System | 26 Mar 2021 19:57:59 |
| User entered 'VISIT4' | System | 26 Mar 2021 19:46:15 |

US3172224

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 22 Apr 2021 16:25:36 |
| User entered 'No (N)' | Jessie Downs (b) (4) (b) (4) | 01 Apr 2021 20:12:12 |

US3172224

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 22 Apr 2021 16:25:36 |
| User entered empty. | Jessie Downs (b) (4) (b) (4) | 01 Apr 2021 20:12:12 |

US3172224

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 22 Apr 2021 16:25:36 |
| User entered empty. | Jessie Downs (b) (4) (b) (4) | 01 Apr 2021 20:12:12 |

US3172224

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 01 Apr 2021 20:12:12 |

US3172224

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 22 Apr 2021 16:25:36 |
| User entered empty. | Jessie Downs (b) (4) (b) (4) | 01 Apr 2021 20:12:12 |

US3172224

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

[Route of measurement](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 22 Apr 2021 16:25:36 |
| User entered empty. | Jessie Downs (b) (4) (b) (4) | 01 Apr 2021 20:12:12 |

US3172224

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 22 Apr 2021 16:25:36 |
| User entered empty. | Jessie Downs (b) (4) (b) (4) | 01 Apr 2021 20:12:12 |

US3172224

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 22 Apr 2021 16:25:36 |
| User entered empty. | Jessie Downs (b) (4) (b) (4) | 01 Apr 2021 20:12:12 |

US3172224

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

[Pulse units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 01 Apr 2021 20:12:12 |

US3172224

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 22 Apr 2021 16:25:36 |
| User entered empty. | Jessie Downs (b) (4) (b) (4) | 01 Apr 2021 20:12:12 |

US3172224

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 01 Apr 2021 20:12:12 |

US3172224

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 22 Apr 2021 16:25:36 |
| User entered empty. | Jessie Downs (b) (4) (b) (4) | 01 Apr 2021 20:12:12 |

US3172224

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 01 Apr 2021 20:12:12 |

US3172224

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 22 Apr 2021 16:25:36 |
| User entered empty. | Jessie Downs (b) (4) (b) (4) | 01 Apr 2021 20:12:12 |

US3172224

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 01 Apr 2021 20:12:12 |

US3172224

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:33:17

Was the physical examination performed?

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) | 22 Apr 2021 16:25:33 |
| | (b) (4) | |
| User entered 'No (N)' reason for change: Data Entry Error | Jessie Downs (b) (4) | 01 Apr 2021 20:12:17 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4) | |
| Query 'Data is required. Please complete.' answered with 'Data added in error' (Site from System). | (b) (4), (b) (6) | 31 Mar 2021 06:48:36 |
| User opened query 'Data is required. Please complete.' (Site from System). | Jessie Downs (b) (4) | 26 Mar 2021 19:58:20 |
| User entered empty; reason for change Data Entry Error | (b) (4) | |
| User entered 'No (N)' | System | 26 Mar 2021 19:57:48 |
| | Jessie Downs (b) (4) | 26 Mar 2021 19:57:48 |
| | (b) (4) | |
| | Jessie Downs (b) (4) | 26 Mar 2021 19:56:47 |
| | (b) (4) | |

US3172224

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:33:17

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 22 Apr 2021 16:25:33 |
| User entered empty. | Jessie Downs (b) (4) (b) (4) | 26 Mar 2021 19:56:47 |

US3172224

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:33:17

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) | 22 Apr 2021 16:25:33 |
| | (b) (4) | |
| User entered 'No (N)' reason for change: Data Entry Error | Jessie Downs (b) (4) | 01 Apr 2021 20:12:22 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4) | |
| Query 'Data is required. Please complete.' answered with 'Data added in error' (Site from System). | (b) (4), (b) (6) | 31 Mar 2021 06:53:22 |
| User opened query 'Data is required. Please complete.' (Site from System). | Jessie Downs (b) (4) | 26 Mar 2021 19:58:24 |
| User entered empty; reason for change Data Entry Error | (b) (4) | |
| User entered 'Yes (Y)' | System | 26 Mar 2021 19:57:43 |
| | Jessie Downs (b) (4) | 26 Mar 2021 19:57:43 |
| | (b) (4) | |
| | Jessie Downs (b) (4) | 26 Mar 2021 19:57:06 |
| | (b) (4) | |

US3172224

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:33:17

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) | 22 Apr 2021 16:25:33 |
| | (b) (4) | |
| User entered empty; reason for change Data Entry Error | Jessie Downs (b) (4) | 26 Mar 2021 19:57:43 |
| | (b) (4) | |
| User entered '19 Mar 2021' | Jessie Downs (b) (4) | 26 Mar 2021 19:57:06 |
| | (b) (4) | |

US3172224

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:33:17

Collection time (00:00-23:59)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 22 Apr 2021 16:25:33 |
| User entered empty; reason for change Data Entry Error | Jessie Downs (b) (4) (b) (4) | 26 Mar 2021 19:57:43 |
| User entered '10:06' | Jessie Downs (b) (4) (b) (4) | 26 Mar 2021 19:57:06 |

US3172224

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered empty. | System | 26 Mar 2021 19:57:43 |
| User entered '19 Mar 2021 10:06' | System | 26 Mar 2021 19:57:06 |

US3172224

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:17

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) | 22 Apr 2021 16:25:33 |
| | (b) (4) | |
| | | |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Jessie Downs (b) (4) | 01 Apr 2021 20:12:28 |
| | (b) (4) | |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4), (b) (6) | 31 Mar 2021 06:48:27 |
| | | |
| Query 'Data is required. Please complete.' answered with 'Data added in error' (Site from System). | Jessie Downs (b) (4) | 26 Mar 2021 19:58:28 |
| | (b) (4) | |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 26 Mar 2021 19:57:23 |
| | | |
| User entered empty; reason for change Data Entry Error | Jessie Downs (b) (4) | 26 Mar 2021 19:57:23 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Jessie Downs (b) (4) | 26 Mar 2021 19:57:10 |
| | (b) (4) | |

US3172224

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:17

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '1' | System | 01 Apr 2021 20:12:28 |
| User entered empty. | System | 26 Mar 2021 19:57:23 |
| User entered '1' | System | 26 Mar 2021 19:57:10 |

US3172224

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:17

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 22 Apr 2021 16:25:33 |
| User entered 'Yes (Y)' | Jessie Downs (b) (4) (b) (4) | 16 Apr 2021 16:26:19 |

US3172224

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:17

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 22 Apr 2021 16:25:33 |
| User entered '14 Apr 2021' | Jessie Downs (b) (4) (b) (4) | 16 Apr 2021 16:26:19 |

US3172224

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:17

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 22 Apr 2021 16:25:33 |
| User entered 'Contact Made (CONTACT MADE)' | Jessie Downs (b) (4) (b) (4) | 16 Apr 2021 16:26:19 |

US3172224

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:17

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 22 Apr 2021 16:25:33 |
| User entered empty. | Jessie Downs (b) (4) (b) (4) | 16 Apr 2021 16:26:19 |

US3172224

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:17

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 22 Apr 2021 16:25:33 |
| User entered 'Yes (Y)' | Jessie Downs (b) (4) (b) (4) | 16 Apr 2021 16:26:24 |

US3172224

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:17

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 16 Apr 2021 16:26:24 |

US3172224

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

Form: Visit Date

Generated On: 09 Jun 2021 15:33:17

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'Yes (Y)' | Jessie Downs (b) (4) (b) (4) | 06 Feb 2021 19:35:49 |

US3172224

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

Form: Visit Date

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered '29 Jan 2021' | Jessie Downs (b) (4) (b) (4) | 06 Feb 2021 19:35:49 |

US3172224

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

Form: Visit Date

Generated On: 09 Jun 2021 15:33:17

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 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'Clinic (Clinic)' | Jessie Downs (b) (4) (b) (4) | 06 Feb 2021 19:35:49 |

US3172224

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

Form: Visit Date

Generated On: 09 Jun 2021 15:33:17

[Folder OID](#)

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User entered 'UNBLND_DECIDE' | System | 06 Feb 2021 19:35:49 |

US3172224

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

Form: Unblinding

Generated On: 09 Jun 2021 15:33:17

Date of updated informed consent (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 22 Apr 2021 16:25:33 |
| User closed query 'PER CDM: RE-QUERY: Per response data updated. However, still date is 22 DEC 2020 and protocol version is Amendment 6 or later. Please review/reconcile and update the data as appropriate. Thank you' (Site from DM). | (b) (4), (b) (6) | 21 Apr 2021 07:19:01 |
| Query 'PER CDM: RE-QUERY: Per response data updated. However, still date is 22 DEC 2020 and protocol version is Amendment 6 or later. Please review/reconcile and update the data as appropriate. Thank you' answered with 'Data was updated.' (Site from DM). | Jessie Downs (b) (4) (b) (4) | 20 Apr 2021 14:49:20 |
| Signature has been broken. | Jessie Downs (b) (4) (b) (4) | 20 Apr 2021 14:48:58 |
| User entered '06 Jan 2021' reason for change: Data Entry Error | Jessie Downs (b) (4) (b) (4) | 20 Apr 2021 14:48:58 |
| User opened query 'PER CDM: RE-QUERY: Per response data updated. However, still date is 22 DEC 2020 and protocol version is Amendment 6 or later. Please review/reconcile and update the data as appropriate. Thank you' (Site from DM). | (b) (4), (b) (6) | 19 Apr 2021 13:37:35 |
| User closed query 'Per sponsor review, This field relates to Amendment 6. The Amendment 6 consent form was not available until 29DEC2020. Please review and update field to the date the subject signed the Amendment 6 or later consent form. If the subject was unblinded and discontinued under Amendment 5, please tick the box below indicating that the consent field is N/A and the subject was unblinded and discontinued under Amendment 5.' (Site from DM). | (b) (4), (b) (6) | 19 Apr 2021 13:37:35 |

US3172224

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

Form: Unblinding

Generated On: 09 Jun 2021 15:33:17

Date of updated informed consent (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|---|----------------------|
| Query 'Per sponsor review, This field relates to Amendment 6. The Amendment 6 consent form was not available until 29DEC2020. Please review and update field to the date the subject signed the Amendment 6 or later consent form. If the subject was unblinded and discontinued under Amendment 5, please tick the box below indicating that the consent field is N/A and the subject was unblinded and discontinued under Amendment 5.' answered with 'Data was updated.' (Site from DM). | Jessie Downs (b) (4) (b) (4) | 07 Apr 2021 19:59:05 |
| User opened query 'Per sponsor review, This field relates to Amendment 6. The Amendment 6 consent form was not available until 29DEC2020. Please review and update field to the date the subject signed the Amendment 6 or later consent form. If the subject was unblinded and discontinued under Amendment 5, please tick the box below indicating that the consent field is N/A and the subject was unblinded and discontinued under Amendment 5.' (Site from DM). | (b) (4), (b) (6) (b) (4) | 07 Apr 2021 17:20:35 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered '22 Dec 2020' | Jessie Downs (b) (4) (b) (4) | 06 Feb 2021 19:37:26 |

US3172224

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

Form: Unblinding

Generated On: 09 Jun 2021 15:33:17

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

| Audit | User | Time (GMT) |
|--|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) | 12 Mar 2021 20:14:01 |
| | (b) (4) | |
| User entered '0' WR# 5295537 | System | 10 Mar 2021 16:55:28 |
| Amendment Manager inserted this DataPoint. | System | 06 Mar 2021 17:06:46 |

US3172224

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

Form: Unblinding

Generated On: 09 Jun 2021 15:33:17

[Was the participant unblinded?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'Yes (Y)' | Jessie Downs (b) (4) (b) (4) | 06 Feb 2021 19:37:26 |

US3172224

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

Form: Unblinding

Generated On: 09 Jun 2021 15:33:17

[Under what version of the Protocol was the Participant unblinded?](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 22 Apr 2021 16:25:33 |
| User closed query ' Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update field. | (b) (4), (b) (6) | 15 Apr 2021 20:06:18 |
| ' (Site from DM). Query ' Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update field. | (b) (4), (b) (6) | 12 Apr 2021 13:06:03 |
| ' answered with 'Data updated' (Site from DM). User entered 'Amendment 6 or later (Amendment 6 or later)' reason for change: Data Entry Error | (b) (4), (b) (6) | 12 Apr 2021 13:05:36 |
| User opened query ' Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update field. | (b) (4), (b) (6) | 09 Apr 2021 21:42:13 |
| ' (Site from DM). Signature has been broken. | Jessie Downs (b) (4) (b) (4) | 07 Apr 2021 19:58:51 |
| User entered 'Amendment 5 (Amendment 5)' reason for change: Data Entry Error | Jessie Downs (b) (4) (b) (4) | 07 Apr 2021 19:58:51 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 12 Mar 2021 20:14:01 |
| User entered empty. WR# 5295537 | System | 10 Mar 2021 16:55:28 |
| Amendment Manager inserted this DataPoint. | System | 06 Mar 2021 17:06:46 |

US3172224

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

Form: Unblinding

Generated On: 09 Jun 2021 15:33:17

Date of unblinding (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 22 Apr 2021 16:25:33 |
| User closed query 'Per IRT, subject was unblinded on 29JAN2021. Please review and reconcile.' (Site from DM). | (b) (4), (b) (6) | 15 Apr 2021 20:06:20 |
| Query 'Per IRT, subject was unblinded on 29JAN2021. Please review and reconcile.' answered with 'Data updated ' (Site from DM). | (b) (4), (b) (6) | 12 Apr 2021 13:06:21 |
| User entered '29 Jan 2021' reason for change: Data Entry Error | (b) (4), (b) (6) | 12 Apr 2021 13:05:36 |
| User opened query 'Per IRT, subject was unblinded on 29JAN2021. Please review and reconcile.' (Site from DM). | (b) (4), (b) (6) | 08 Apr 2021 17:10:39 |
| Signature has been broken. | Jessie Downs (b) (4) (b) (4) | 22 Mar 2021 19:00:48 |
| User entered '19 Mar 2021' reason for change: Data Entry Error | Jessie Downs (b) (4) (b) (4) | 22 Mar 2021 19:00:48 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered '29 Jan 2021' | Jessie Downs (b) (4) (b) (4) | 06 Feb 2021 19:37:26 |

US3172224

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

Form: Unblinding

Generated On: 09 Jun 2021 15:33:17

[Participant randomization assignment](#)

| Audit | User | Time (GMT) |
|----------------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'Placebo (Placebo)' | Jessie Downs (b) (4) (b) (4) | 06 Feb 2021 19:37:26 |

US3172224

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

Form: Unblinding

Generated On: 09 Jun 2021 15:33:17

[Actual Dose 1](#)

| Audit | User | Time (GMT) |
|----------------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'Placebo (Placebo)' | Jessie Downs (b) (4) (b) (4) | 06 Feb 2021 19:37:26 |

US3172224

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

Form: Unblinding

Generated On: 09 Jun 2021 15:33:17

[Actual Dose 2](#)

| Audit | User | Time (GMT) |
|----------------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'Placebo (Placebo)' | Jessie Downs (b) (4) (b) (4) | 06 Feb 2021 19:37:26 |

US3172224

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

Form: Unblinding

Generated On: 09 Jun 2021 15:33:17

[Will participant receive mRNA-1273?](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 22 Apr 2021 16:25:33 |
| Signature has been broken. | Jessie Downs (b) (4) (b) (4) | 22 Mar 2021 19:00:48 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Jessie Downs (b) (4) (b) (4) | 22 Mar 2021 19:00:48 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'No (N)' | Jessie Downs (b) (4) (b) (4) | 06 Feb 2021 19:37:26 |

US3172224

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

Form: Unblinding

Generated On: 09 Jun 2021 15:33:17

[Placebo Only Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User entered '1' | System | 06 Feb 2021 19:37:26 |

US3172224

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

Form: Unblinding

Generated On: 09 Jun 2021 15:33:17

[Continuing with mRNA-1273](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User entered 'I' | System | 22 Mar 2021 19:00:48 |
| User entered empty. | System | 06 Feb 2021 19:37:26 |

US3172224

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:33:17

Height

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 22 Apr 2021 16:25:33 |
| User entered missing code ND - Not Done. | Jessie Downs (b) (4) (b) (4) | 22 Mar 2021 19:02:58 |

US3172224

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:33:17

[Weight](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 22 Apr 2021 16:25:33 |
| User entered '079.7' kg | Jessie Downs (b) (4) (b) (4) | 22 Mar 2021 19:02:58 |

US3172224

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:33:17

BMI (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User entered empty. | System | 22 Mar 2021 19:02:58 |
| DataPoint set to visible. | System | 22 Mar 2021 19:00:48 |

US3172224

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:33:17

[Height](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 22 Apr 2021 16:25:33 |
| User entered missing code ND - Not Done. | Jessie Downs (b) (4) (b) (4) | 22 Mar 2021 19:02:58 |

US3172224

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:33:17

[Weight](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 22 Apr 2021 16:25:33 |
| User entered '079.7' kg | Jessie Downs (b) (4) (b) (4) | 22 Mar 2021 19:02:58 |

US3172224

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:33:17

BMI (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User entered empty. | System | 22 Mar 2021 19:02:58 |
| DataPoint set to visible. | System | 22 Mar 2021 19:00:48 |

US3172224

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User accepted default value 'Pre-Dose (PREDOSE)' | Jessie Downs (b) (4) (b) (4) | 22 Mar 2021 19:02:58 |

US3172224

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 22 Apr 2021 16:25:33 |
| User entered 'Yes (Y)' | Jessie Downs (b) (4) (b) (4) | 22 Mar 2021 19:02:58 |

US3172224

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 22 Apr 2021 16:25:33 |
| User entered '19 Mar 2021' | Jessie Downs (b) (4) (b) (4) | 22 Mar 2021 19:02:58 |

US3172224

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) | 22 Apr 2021 16:25:33 |
| | (b) (4) | |
| User entered '13:10' | Jessie Downs (b) (4) | 22 Mar 2021 19:02:58 |
| | (b) (4) | |

US3172224

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User entered '19 Mar 2021 13:10' | System | 22 Mar 2021 19:02:58 |

US3172224

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 22 Apr 2021 16:25:33 |
| User entered '37.2' C | Jessie Downs (b) (4) (b) (4) | 22 Mar 2021 19:02:58 |

US3172224

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 22 Apr 2021 16:25:33 |
| User entered 'Oral (Oral)' | Jessie Downs (b) (4) (b) (4) | 22 Mar 2021 19:02:58 |

US3172224

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 22 Apr 2021 16:25:33 |
| User entered empty. | Jessie Downs (b) (4) (b) (4) | 22 Mar 2021 19:02:58 |

US3172224

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) | 22 Apr 2021 16:25:33 |
| | (b) (4) | |
| User entered '89' | Jessie Downs (b) (4) | 22 Mar 2021 19:02:58 |
| | (b) (4) | |

US3172224

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User entered 'bpm' | System | 22 Mar 2021 19:02:58 |

US3172224

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 22 Apr 2021 16:25:33 |
| User entered '17' | Jessie Downs (b) (4) (b) (4) | 22 Mar 2021 19:02:58 |

US3172224

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User entered 'breaths/min' | System | 22 Mar 2021 19:02:58 |

US3172224

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 22 Apr 2021 16:25:33 |
| User entered '112' | Jessie Downs (b) (4) (b) (4) | 22 Mar 2021 19:02:58 |

US3172224

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User entered 'mmHg' | System | 22 Mar 2021 19:02:58 |

US3172224

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 22 Apr 2021 16:25:33 |
| User entered '73' | Jessie Downs (b) (4) (b) (4) | 22 Mar 2021 19:02:58 |

US3172224

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User entered 'mmHg' | System | 22 Mar 2021 19:02:58 |

US3172224

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:33:17

Height

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 22 Apr 2021 16:25:33 |
| User entered missing code ND - Not Done. | Jessie Downs (b) (4) (b) (4) | 22 Mar 2021 19:02:58 |

US3172224

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:33:17

[Weight](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 22 Apr 2021 16:25:33 |
| User entered '079.7' kg | Jessie Downs (b) (4) (b) (4) | 22 Mar 2021 19:02:58 |

US3172224

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:33:17

BMI (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User entered empty. | System | 22 Mar 2021 19:02:58 |
| DataPoint set to visible. | System | 22 Mar 2021 19:00:48 |

US3172224

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User accepted default value 'Post-Dose (POSTDOSE)' | Jessie Downs (b) (4) (b) (4) | 22 Mar 2021 19:02:58 |

US3172224

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 22 Apr 2021 16:25:33 |
| User entered 'Yes (Y)' | Jessie Downs (b) (4) (b) (4) | 22 Mar 2021 19:02:58 |

US3172224

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 22 Apr 2021 16:25:33 |
| User entered '19 Mar 2021' | Jessie Downs (b) (4) (b) (4) | 22 Mar 2021 19:02:58 |

US3172224

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) | 22 Apr 2021 16:25:33 |
| | (b) (4) | |
| User entered '15:12' | Jessie Downs (b) (4) | 22 Mar 2021 19:02:58 |
| | (b) (4) | |

US3172224

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User entered '19 Mar 2021 15:12' | System | 22 Mar 2021 19:02:58 |

US3172224

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 22 Apr 2021 16:25:33 |
| User entered '36.6' C | Jessie Downs (b) (4) (b) (4) | 22 Mar 2021 19:02:58 |

US3172224

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 22 Apr 2021 16:25:33 |
| User entered 'Oral (Oral)' | Jessie Downs (b) (4) (b) (4) | 22 Mar 2021 19:02:58 |

US3172224

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 22 Apr 2021 16:25:33 |
| User entered empty. | Jessie Downs (b) (4) (b) (4) | 22 Mar 2021 19:02:58 |

US3172224

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 22 Apr 2021 16:25:33 |
| User entered '61' | Jessie Downs (b) (4) (b) (4) | 22 Mar 2021 19:02:58 |

US3172224

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User entered 'bpm' | System | 22 Mar 2021 19:02:58 |

US3172224

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 22 Apr 2021 16:25:33 |
| User entered '16' | Jessie Downs (b) (4) (b) (4) | 22 Mar 2021 19:02:58 |

US3172224

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User entered 'breaths/min' | System | 22 Mar 2021 19:02:58 |

US3172224

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 22 Apr 2021 16:25:33 |
| User entered '123' | Jessie Downs (b) (4) (b) (4) | 22 Mar 2021 19:02:58 |

US3172224

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User entered 'mmHg' | System | 22 Mar 2021 19:02:58 |

US3172224

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 22 Apr 2021 16:25:33 |
| User entered '80' | Jessie Downs (b) (4) (b) (4) | 22 Mar 2021 19:02:58 |

US3172224

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User entered 'mmHg' | System | 22 Mar 2021 19:02:58 |

US3172224

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

Form: Physical Examination

Generated On: 09 Jun 2021 15:33:17

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 22 Apr 2021 16:25:33 |
| User entered 'Yes (Y)' | Jessie Downs (b) (4) (b) (4) | 22 Mar 2021 19:01:11 |

US3172224

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

Form: Physical Examination

Generated On: 09 Jun 2021 15:33:17

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 22 Apr 2021 16:25:33 |
| User entered '19 Mar 2021' | Jessie Downs (b) (4) (b) (4) | 22 Mar 2021 19:01:11 |

US3172224

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

Form: Exposure

Generated On: 09 Jun 2021 15:33:17

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 22 Apr 2021 16:25:33 |
| User entered 'Yes (Y)' | Jessie Downs (b) (4) (b) (4) | 22 Mar 2021 19:01:30 |

US3172224

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

Form: Exposure

Generated On: 09 Jun 2021 15:33:17

[If No, reason not given](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) | 22 Apr 2021 16:25:33 |
| | (b) (4) | |
| User entered empty. | Jessie Downs (b) (4) | 22 Mar 2021 19:01:30 |
| | (b) (4) | |

US3172224

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

Form: Exposure

Generated On: 09 Jun 2021 15:33:17

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) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 22 Apr 2021 16:25:33 |
| User entered empty. | Jessie Downs (b) (4) (b) (4) | 22 Mar 2021 19:01:30 |

US3172224

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

Form: Exposure

Generated On: 09 Jun 2021 15:33:17

[What was the study treatment? \(Unblinded\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User entered 'mRNA-1273' | System | 22 Mar 2021 19:01:30 |
| DataPoint set to visible. | System | 22 Mar 2021 19:00:48 |

US3172224

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

Form: Exposure

Generated On: 09 Jun 2021 15:33:17

What was the treatment date? (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) | 22 Apr 2021 16:25:33 |
| | (b) (4) | |
| User entered '19 Mar 2021' | Jessie Downs (b) (4) | 22 Mar 2021 19:01:30 |
| | (b) (4) | |

US3172224

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

Form: Exposure

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 22 Apr 2021 16:25:33 |
| User entered '14:42' | Jessie Downs (b) (4) (b) (4) | 22 Mar 2021 19:01:30 |

US3172224

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

Form: Exposure

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User entered '19 Mar 2021 14:42' | System | 22 Mar 2021 19:01:30 |

US3172224

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

Form: Exposure

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|--------------------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 22 Apr 2021 16:25:33 |
| User entered 'Right Arm (RIGHT ARM)' | Jessie Downs (b) (4) (b) (4) | 22 Mar 2021 19:01:30 |

US3172224

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

Form: Exposure

Generated On: 09 Jun 2021 15:33:17

What was the frequency of the study treatment dosing?

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User entered 'ONCE' | System | 22 Mar 2021 19:01:30 |

US3172224

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

Form: Exposure

Generated On: 09 Jun 2021 15:33:17

What was the route of administration for the study treatment?

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User entered 'INTRAMUSCULAR' | System | 22 Mar 2021 19:01:30 |

US3172224

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:33:17

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'Yes (Y)' | Jessie Downs (b) (4) (b) (4) | 06 Feb 2021 19:36:11 |

US3172224

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:33:17

Collection date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered '29 Jan 2021' | Jessie Downs (b) (4) (b) (4) | 06 Feb 2021 19:36:11 |

US3172224

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:33:17

Collection time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered '13:35' | Jessie Downs (b) (4) (b) (4) | 06 Feb 2021 19:36:11 |

US3172224

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User entered '29 Jan 2021 13:35' | System | 06 Feb 2021 19:36:11 |

US3172224

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:33:17

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'Yes (Y)' | Jessie Downs (b) (4) (b) (4) | 06 Feb 2021 19:36:37 |

US3172224

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:33:17

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered '29 Jan 2021' | Jessie Downs (b) (4) (b) (4) | 06 Feb 2021 19:36:37 |

US3172224

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:33:17

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered '13:36' | Jessie Downs (b) (4) (b) (4) | 06 Feb 2021 19:36:37 |

US3172224

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User entered '29 Jan 2021 13:36' | System | 06 Feb 2021 19:36:37 |

US3172224

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

Form: Continuing

Generated On: 09 Jun 2021 15:33:17

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 22 Apr 2021 16:25:33 |
| User entered 'Yes (Y)' | Jessie Downs (b) (4) (b) (4) | 22 Mar 2021 19:01:34 |

US3172224

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

Form: Continuing

Generated On: 09 Jun 2021 15:33:17

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 08:21:53 |
| User entered 'I' | System | 22 Mar 2021 19:01:34 |

US3172224

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:17

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 07:42:32 |
| | | |
| User signature succeeded. | Mark Kutner (b) (4) | 22 Apr 2021 16:25:33 |
| | (b) (4) | |
| | | |
| User entered 'Yes (Y)' | Jessie Downs (b) (4) | 26 Mar 2021 19:31:46 |
| | (b) (4) | |

US3172224

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:17

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 07:42:32 |
| | | |
| User signature succeeded. | Mark Kutner (b) (4) | 22 Apr 2021 16:25:33 |
| | (b) (4) | |
| | | |
| User entered '26 Mar 2021' | Jessie Downs (b) (4) | 26 Mar 2021 19:31:46 |
| | (b) (4) | |

US3172224

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:17

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 07:42:32 |
| | | |
| User signature succeeded. | Mark Kutner (b) (4) | 22 Apr 2021 16:25:33 |
| | (b) (4) | |
| | | |
| User entered 'Contact Made (CONTACT MADE)' | Jessie Downs (b) (4) | 26 Mar 2021 19:31:46 |
| | (b) (4) | |

US3172224

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:17

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 07:42:32 |
| | | |
| User signature succeeded. | Mark Kutner (b) (4) | 22 Apr 2021 16:25:33 |
| | (b) (4) | |
| | | |
| User entered empty. | Jessie Downs (b) (4) | 26 Mar 2021 19:31:46 |
| | (b) (4) | |

US3172224

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:17

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 07:42:32 |
| | | |
| User signature succeeded. | Mark Kutner (b) (4) | 22 Apr 2021 16:25:33 |
| | (b) (4) | |
| | | |
| User entered 'Yes (Y)' | Jessie Downs (b) (4) | 26 Mar 2021 19:32:34 |
| | (b) (4) | |

US3172224

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:17

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 07:42:32 |
| | | |
| User entered 'I' | System | 26 Mar 2021 19:32:34 |

US3172224

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:17

[OLD29 Placebo Flag](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 07:42:32 |
| | | |
| User entered 'I' | System | 26 Mar 2021 19:32:34 |
| DataPoint set to visible. | System | 26 Mar 2021 19:32:34 |

US3172224

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:33:17

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 22 Apr 2021 16:25:33 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) (b) (4) | 21 Apr 2021 20:23:20 |

US3172224

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 22 Apr 2021 16:25:33 |
| User entered '13 Apr 2021' | (b) (4), (b) (6) (b) (4) | 21 Apr 2021 20:23:20 |

US3172224

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|--------------------------------|--------------------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 22 Apr 2021 16:25:33 |
| User entered 'Clinic (Clinic)' | (b) (4), (b) (6) (b) (4) | 21 Apr 2021 20:23:20 |

US3172224

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:33:17

[Folder OID](#)

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| User entered 'OLD29' | System | 21 Apr 2021 20:23:20 |

US3172224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| User accepted default value 'Pre-Dose (PREDOSE)' | (b) (4), (b) (6) | 21 Apr 2021 20:24:50 |
| | | |

US3172224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 22 Apr 2021 16:25:33 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) (b) (4) | 21 Apr 2021 20:24:50 |

US3172224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 22 Apr 2021 16:25:33 |
| User entered '13 Apr 2021' | (b) (4), (b) (6) (b) (4) | 21 Apr 2021 20:24:50 |

US3172224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 22 Apr 2021 16:25:33 |
| User entered '13:50' | (b) (4), (b) (6) (b) (4) | 21 Apr 2021 20:24:50 |

US3172224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '13 Apr 2021 13:50' | System | 21 Apr 2021 20:24:50 |

US3172224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 22 Apr 2021 16:25:33 |
| User entered '36.7' C | (b) (4), (b) (6) (b) (4) | 21 Apr 2021 20:24:50 |

US3172224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 22 Apr 2021 16:25:33 |
| User entered 'Oral (Oral)' | (b) (4), (b) (6) (b) (4) | 21 Apr 2021 20:24:50 |

US3172224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 22 Apr 2021 16:25:33 |
| User entered empty. | (b) (4), (b) (6) (b) (4) | 21 Apr 2021 20:24:50 |

US3172224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 22 Apr 2021 16:25:33 |
| User entered '80' | (b) (4), (b) (6) (b) (4) | 21 Apr 2021 20:24:50 |

US3172224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 21 Apr 2021 20:24:50 |

US3172224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 22 Apr 2021 16:25:33 |
| User entered '15' | (b) (4), (b) (6) (b) (4) | 21 Apr 2021 20:24:50 |

US3172224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 21 Apr 2021 20:24:50 |

US3172224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 22 Apr 2021 16:25:33 |
| User entered '108' | (b) (4), (b) (6) (b) (4) | 21 Apr 2021 20:24:50 |

US3172224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 21 Apr 2021 20:24:50 |

US3172224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 22 Apr 2021 16:25:33 |
| User entered '72' | (b) (4), (b) (6) (b) (4) | 21 Apr 2021 20:24:50 |

US3172224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 21 Apr 2021 20:24:50 |

US3172224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| User accepted default value 'Post-Dose (POSTDOSE)' | (b) (4), (b) (6) | 21 Apr 2021 20:24:50 |

US3172224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 22 Apr 2021 16:25:33 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) (b) (4) | 21 Apr 2021 20:24:50 |

US3172224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 22 Apr 2021 16:25:33 |
| User entered '13 Apr 2021' | (b) (4), (b) (6) (b) (4) | 21 Apr 2021 20:24:50 |

US3172224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 22 Apr 2021 16:25:33 |
| User entered '15:23' | (b) (4), (b) (6) (b) (4) | 21 Apr 2021 20:24:50 |

US3172224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '13 Apr 2021 15:23' | System | 21 Apr 2021 20:24:50 |

US3172224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 22 Apr 2021 16:25:33 |
| User entered '36.8' C | (b) (4), (b) (6) (b) (4) | 21 Apr 2021 20:24:50 |

US3172224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 22 Apr 2021 16:25:33 |
| User entered 'Oral (Oral)' | (b) (4), (b) (6) (b) (4) | 21 Apr 2021 20:24:50 |

US3172224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 22 Apr 2021 16:25:33 |
| User entered empty. | (b) (4), (b) (6) (b) (4) | 21 Apr 2021 20:24:50 |

US3172224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 22 Apr 2021 16:25:33 |
| User entered '60' | (b) (4), (b) (6) (b) (4) | 21 Apr 2021 20:24:50 |

US3172224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 21 Apr 2021 20:24:50 |

US3172224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 22 Apr 2021 16:25:33 |
| User entered '16' | (b) (4), (b) (6) (b) (4) | 21 Apr 2021 20:24:50 |

US3172224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 21 Apr 2021 20:24:50 |

US3172224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 22 Apr 2021 16:25:33 |
| User entered '122' | (b) (4), (b) (6) (b) (4) | 21 Apr 2021 20:24:50 |

US3172224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 21 Apr 2021 20:24:50 |

US3172224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 22 Apr 2021 16:25:33 |
| User entered '78' | (b) (4), (b) (6) (b) (4) | 21 Apr 2021 20:24:50 |

US3172224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 21 Apr 2021 20:24:50 |

US3172224

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:33:17

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 22 Apr 2021 16:25:33 |
| User entered 'No (N)' | (b) (4), (b) (6) | 21 Apr 2021 20:24:56 |

US3172224

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:33:17

Date of examination (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 22 Apr 2021 16:25:33 |
| User entered empty. | (b) (4), (b) (6) (b) (4), (b) (6) | 21 Apr 2021 20:24:56 |

US3172224

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:33:17

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 22 Apr 2021 16:25:33 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) (b) (4) | 21 Apr 2021 20:25:25 |

US3172224

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:33:17

[If No, reason not given](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 22 Apr 2021 16:25:33 |
| User entered empty. | (b) (4), (b) (6) (b) (4) | 21 Apr 2021 20:25:25 |

US3172224

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 22 Apr 2021 16:25:33 |
| User entered empty. | (b) (4), (b) (6) (b) (4), (b) (6) | 21 Apr 2021 20:25:25 |

US3172224

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:33:17

[What was the study treatment? \(Unblinded\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------|----------------------|
| User entered 'mRNA-1273' | System | 21 Apr 2021 20:25:25 |
| DataPoint set to visible. | System | 26 Mar 2021 19:32:34 |

US3172224

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:33:17

What was the treatment date? (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 22 Apr 2021 16:25:33 |
| User entered '13 Apr 2021' | (b) (4), (b) (6) (b) (4) | 21 Apr 2021 20:25:25 |

US3172224

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 22 Apr 2021 16:25:33 |
| User entered '14:53' | (b) (4), (b) (6) (b) (4) | 21 Apr 2021 20:25:25 |

US3172224

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '13 Apr 2021 14:53' | System | 21 Apr 2021 20:25:25 |

US3172224

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|--------------------------------------|--------------------------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 22 Apr 2021 16:25:33 |
| User entered 'Right Arm (RIGHT ARM)' | (b) (4), (b) (6) (b) (4), (b) (6) | 21 Apr 2021 20:25:25 |

US3172224

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:33:17

What was the frequency of the study treatment dosing?

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered 'ONCE' | System | 21 Apr 2021 20:25:25 |

US3172224

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:33:17

What was the route of administration for the study treatment?

| Audit | User | Time (GMT) |
|------------------------------|--------|----------------------|
| User entered 'INTRAMUSCULAR' | System | 21 Apr 2021 20:25:25 |

US3172224

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:17

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 22 Apr 2021 16:25:33 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) (b) (4) | 21 Apr 2021 20:25:32 |

US3172224

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:17

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 21 Apr 2021 20:25:32 |

US3172224

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:17

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 22 Apr 2021 16:25:33 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 21 Apr 2021 20:25:48 |

US3172224

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:17

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 22 Apr 2021 16:25:33 |
| User entered '21 Apr 2021' | (b) (4), (b) (6) (b) (4) | 21 Apr 2021 20:25:48 |

US3172224

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:17

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|--------------------------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 22 Apr 2021 16:25:33 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4), (b) (6) (b) (4), (b) (6) | 21 Apr 2021 20:25:48 |

US3172224

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:17

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 22 Apr 2021 16:25:33 |
| User entered empty. | (b) (4), (b) (6) | 21 Apr 2021 20:25:48 |

US3172224

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:17

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 22 Apr 2021 16:25:33 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) (b) (4) | 21 Apr 2021 20:25:54 |

US3172224

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:17

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 21 Apr 2021 20:25:54 |

US3172224

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:33:17

[Did the participant experience any adverse events?](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 10:55:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:23:58 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Jessie Downs (b) (4) (b) (4) | 29 Jan 2021 19:45:57 |
| User entered 'No (N)' | Mariete Rendon (b) (4) (b) (4) | 02 Sep 2020 21:05:44 |

US3172224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:17

[AEID](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:26:40 |
| Reviewed for Safety. | (b) (4), (b) (6) | 01 Feb 2021 13:12:33 |
| User entered 'USA-US118-2021-mRNA-1273-P301000004' | System | 01 Feb 2021 13:12:30 |
| User entered 'New' | (b) (4), (b) (6) | 01 Feb 2021 13:12:30 |

US3172224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:17

[Adverse event](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:26:40 |
| User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Chest and respiratory tract injuries NEC, PT: Traumatic haemothorax, LLT: Hemopneumothorax - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 06 Apr 2021 11:09:53 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 06 Apr 2021 11:09:53 |
| User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Chest and respiratory tract injuries NEC, PT: Traumatic haemothorax, LLT: Traumatic pneumohemothorax - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 27 Mar 2021 21:30:18 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 27 Mar 2021 21:30:18 |
| User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Chest and respiratory tract injuries NEC, PT: Traumatic haemothorax, LLT: Hemopneumothorax - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 02 Feb 2021 19:21:36 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 02 Feb 2021 19:21:36 |
| Data point term sent to Coder | System | 29 Jan 2021 19:53:19 |
| User entered 'Hemopneumothorax - secondary to rib cage multiple fractures.' | Jessie Downs (b) (4) (b) (4) | 29 Jan 2021 19:52:48 |

US3172224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:17

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|------------------------|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:26:40 |
| User entered 'Yes (Y)' | Jessie Downs (b) (4) | 29 Jan 2021 19:52:48 |
| | (b) (4) | |

US3172224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:17

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|-----------------------|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:26:40 |
| User entered 'No (N)' | Jessie Downs (b) (4) (b) (4) | 29 Jan 2021 19:52:48 |

US3172224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:17

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|-----------------------|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:26:40 |
| User entered 'No (N)' | Jessie Downs (b) (4) | 29 Jan 2021 19:52:48 |
| | (b) (4) | |

US3172224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:26:40 |
| User entered '23 Jan 2021' | Jessie Downs (b) (4) | 29 Jan 2021 19:52:48 |
| | (b) (4) | |

US3172224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:17

Start time (00:00-23:59)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:26:40 |
| User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System). | System | 29 Jan 2021 19:53:27 |
| User entered empty; reason for change Data Entry Error | Jessie Downs (b) (4) | 29 Jan 2021 19:53:27 |
| User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System). | System | 29 Jan 2021 19:52:48 |
| User entered '12:30' | Jessie Downs (b) (4) | 29 Jan 2021 19:52:48 |

US3172224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:17

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered empty. | System | 29 Jan 2021 19:53:27 |
| User entered '23 Jan 2021 12:30' | System | 29 Jan 2021 19:52:48 |

US3172224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:17

[Ongoing?](#)

| Audit | User | Time (GMT) |
|-----------------------|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:26:40 |
| User entered 'No (N)' | Jessie Downs (b) (4) | 29 Jan 2021 19:52:48 |
| | (b) (4) | |

US3172224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:17

If not Ongoing, end date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:26:40 |
| User entered '27 Jan 2021' | Jessie Downs (b) (4) | 29 Jan 2021 19:52:48 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:17

End time (00:00-23:59)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:26:40 |
| User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System). | System | 29 Jan 2021 19:53:27 |
| User entered empty; reason for change Data Entry Error | Jessie Downs (b) (4) | 29 Jan 2021 19:53:27 |
| User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System). | System | 29 Jan 2021 19:52:48 |
| User entered '07:00' | Jessie Downs (b) (4) | 29 Jan 2021 19:52:48 |

US3172224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:17

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered empty. | System | 29 Jan 2021 19:53:27 |
| User entered '27 Jan 2021 07:00' | System | 29 Jan 2021 19:52:48 |

US3172224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:17

[Severity](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 30 Apr 2021 20:33:28 |
| Query 'Per source, grade 3.' canceled (Site from CRA). | (b) (4), (b) (6) | 30 Apr 2021 20:33:25 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 19 Apr 2021 16:26:48 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:26:40 |
| User opened query 'Per source, grade 3.' (Site from CRA). | (b) (4), (b) (6) | 19 Apr 2021 16:25:45 |
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' | Jessie Downs (b) (4) (b) (4) | 29 Jan 2021 19:52:48 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:17

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:26:40 |
| 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 | 29 Jan 2021 19:53:27 |
| 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 | 29 Jan 2021 19:52:48 |
| User entered 'Yes (Y)' | Jessie Downs (b) (4) (b) (4) | 29 Jan 2021 19:52:48 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:17

[Death](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:26:40 |
| User entered '0' | Jessie Downs (b) (4) | 29 Jan 2021 19:52:48 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:17

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:26:40 |
| User entered '0' | Jessie Downs (b) (4) | 29 Jan 2021 19:52:48 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:17

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:26:40 |
| User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System). | | 29 Jan 2021 20:38:41 |
| Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered by data change (Site from System). | System | 29 Jan 2021 19:53:27 |
| User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System). | System | 29 Jan 2021 19:53:27 |
| User entered '1' reason for change: Data Entry Error | Jessie Downs (b) (4) | 29 Jan 2021 19:52:48 |
| User entered '0' | Jessie Downs (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:17

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:26:40 |
| User entered '23 Jan 2021' reason for change: Data Entry Error | Jessie Downs (b) (4) | 29 Jan 2021 19:54:18 |
| User entered empty. | (b) (4) | |
| | Jessie Downs (b) (4) | 29 Jan 2021 19:52:48 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:17

Hospital Discharge Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:26:40 |
| User entered '27 Jan 2021' reason for change: Data Entry Error | Jessie Downs (b) (4) | 29 Jan 2021 19:54:18 |
| User entered empty. | (b) (4) | |
| | Jessie Downs (b) (4) | 29 Jan 2021 19:52:48 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:17

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:26:40 |
| User entered 'No (N)' reason for change: Data Entry Error | Jessie Downs (b) (4) | 29 Jan 2021 20:38:41 |
| User entered empty. | Jessie Downs (b) (4) | 29 Jan 2021 19:52:48 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:17

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:26:40 |
| User entered empty. | Jessie Downs (b) (4) | 29 Jan 2021 19:52:48 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:17

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:26:40 |
| User entered '0' | Jessie Downs (b) (4) | 29 Jan 2021 19:52:48 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:17

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:26:40 |
| User entered '0' | Jessie Downs (b) (4) | 29 Jan 2021 19:52:48 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:17

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:26:40 |
| User entered '0' | Jessie Downs (b) (4) | 29 Jan 2021 19:52:48 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:17

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:26:40 |
| User entered 'Not Related (NOT RELATED)' | Jessie Downs (b) (4) | 29 Jan 2021 19:52:48 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:17

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:26:40 |
| User entered 'Not Related (NOT RELATED)' | Jessie Downs (b) (4) (b) (4) | 29 Jan 2021 19:52:48 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:17

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:26:40 |
| User entered 'Not Applicable (NOT APPLICABLE)' | Jessie Downs (b) (4) | 29 Jan 2021 19:52:48 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:17

[None](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:26:40 |
| User entered '0' | Jessie Downs (b) (4) | 29 Jan 2021 19:52:48 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:17

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:26:40 |
| User entered '0' | Jessie Downs (b) (4) | 29 Jan 2021 19:52:48 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:17

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:26:40 |
| User closed query 'Per DM CLR: Other Action Taken = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM). | (b) (4), (b) (6) | 05 Mar 2021 06:45:28 |
| Query 'Per DM CLR: Other Action Taken = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' answered with 'pending' (Site from DM). | Jessie Downs (b) (4) (b) (4) | 26 Feb 2021 21:49:58 |
| User opened query 'Per DM CLR: Other Action Taken = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM). | (b) (4), (b) (6) | 19 Feb 2021 05:28:01 |
| User entered 'I' | Jessie Downs (b) (4) (b) (4) | 29 Jan 2021 19:52:48 |

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Folder: Adverse Events

Form: Adverse Events (1)

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[Outcome](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:26:40 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | Jessie Downs (b) (4) (b) (4) | 29 Jan 2021 19:52:48 |

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Folder: Adverse Events

Form: Adverse Events (1)

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:26:40 |
| User entered empty. | Jessie Downs (b) (4) | 29 Jan 2021 19:52:48 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:26:40 |
| User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety). | (b) (4), (b) (6) | 04 Mar 2021 18:27:08 |
| User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety). | (b) (4), (b) (6) | 04 Mar 2021 18:26:56 |
| Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'Pending medical records.' (Site from Safety). | Jessie Downs (b) (4) (b) (4) | 03 Mar 2021 21:44:00 |
| Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'No results are available' (Site from Safety). | Jessie Downs (b) (4) (b) (4) | 03 Mar 2021 21:43:39 |
| User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety). | (b) (4), (b) (6) | 01 Mar 2021 19:36:25 |
| User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety). | (b) (4), (b) (6) | 01 Mar 2021 19:36:25 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:17

[Narrative](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety). | (b) (4), (b) (6) | 01 Mar 2021 19:36:19 |
| User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety). | (b) (4), (b) (6) | 01 Mar 2021 19:36:19 |
| Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'pending' (Site from Safety). | Jessie Downs (b) (4) | 26 Feb 2021 21:50:27 |
| Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'pending' (Site from Safety). | Jessie Downs (b) (4) | 26 Feb 2021 21:50:11 |
| User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety). | (b) (4), (b) (6) | 08 Feb 2021 15:13:25 |
| User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety). | (b) (4), (b) (6) | 08 Feb 2021 15:13:17 |

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| User entered 'Hemopneumothorax secondary to right rib cage multiple fractures due to a motor vehicle accident, requiring hospitalization and thoracotomy. Discharged home, stable and recovered from Hemopneumothorax (Acute / traumatic).' | Jessie Downs (b) (4) | 29 Jan 2021 19:52:48 |

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Folder: Adverse Events

Form: Adverse Events (1)

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 29 Jan 2021 19:52:48 |

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Folder: Adverse Events

Form: Adverse Events (1)

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 29 Jan 2021 19:52:48 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:17

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '0' | System | 29 Jan 2021 20:38:41 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:17

[AEID](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:26:40 |
| Reviewed for Safety. | (b) (4), (b) (6) | 01 Feb 2021 13:13:10 |
| User entered 'USA-US118-2021-mRNA-1273-P301000004' | (b) (4), (b) (6) | 01 Feb 2021 13:12:50 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:17

[Adverse event](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:26:40 |
| User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Bone and joint injuries, HLT: Thoracic cage fractures and dislocations, PT: Rib fracture, LLT: Fractured ribs - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 14 Apr 2021 18:50:59 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 14 Apr 2021 18:50:59 |
| User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Bone and joint injuries, HLT: Thoracic cage fractures and dislocations, PT: Rib fracture, LLT: Fracture rib - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 08 Apr 2021 21:49:07 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 08 Apr 2021 21:49:07 |
| User closed query 'PV Query: The event term 'Right rib cage multiple fractures - secondary to car accident' contains multiple event terms. Please consider reporting 'car accident' as a separate event.' (Site from Safety). | (b) (4), (b) (6) | 08 Apr 2021 14:26:21 |
| Data point term sent to Coder | System | 08 Apr 2021 13:32:06 |
| Query 'PV Query: The event term 'Right rib cage multiple fractures - secondary to car accident' contains multiple event terms. Please consider reporting 'car accident' as a separate event.' answered with 'Data was updated.' (Site from Safety). | Jessie Downs (b) (4) (b) (4) | 08 Apr 2021 13:32:05 |
| Coding entries removed. | Jessie Downs (b) (4) (b) (4) | 08 Apr 2021 13:31:42 |
| User entered 'RIGHT RIB CAGE MULTIPLE FRACTURES' reason for change: Data Entry Error | Jessie Downs (b) (4) (b) (4) | 08 Apr 2021 13:31:42 |
| User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Bone and joint injuries, HLT: Fractures and dislocations NEC, PT: Traumatic fracture, LLT: Traumatic fracture - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 10 Mar 2021 12:10:50 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 10 Mar 2021 12:10:50 |

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Folder: Adverse Events

Form: Adverse Events (2)

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[Adverse event](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User opened query 'PV Query: The event term 'Right rib cage multiple fractures - secondary to car accident' contains multiple event terms. Please consider reporting 'car accident' as a separate event.' (Site from Safety). | (b) (4), (b) (6) | 01 Mar 2021 19:37:16 |
| User closed query 'PV Query: The event term 'Right rib cage multiple fractures - secondary to car accident' contains multiple event terms. Please consider reporting 'car accident' as a separate event.' (Site from Safety). | (b) (4), (b) (6) | 01 Mar 2021 19:37:16 |
| Query 'PV Query: The event term 'Right rib cage multiple fractures - secondary to car accident' contains multiple event terms. Please consider reporting 'car accident' as a separate event.' answered with 'data confirmed as entered.' (Site from Safety). | Jessie Downs (b) (4) (b) (4) | 26 Feb 2021 21:51:05 |
| User opened query 'PV Query: The event term 'Right rib cage multiple fractures - secondary to car accident' contains multiple event terms. Please consider reporting 'car accident' as a separate event.' (Site from Safety). | (b) (4), (b) (6) | 08 Feb 2021 15:12:14 |
| Data point term sent to Coder | System | 29 Jan 2021 20:02:53 |
| User entered 'Right rib cage multiple fractures - secondary to car accident' | Jessie Downs (b) (4) (b) (4) | 29 Jan 2021 20:02:31 |

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Folder: Adverse Events

Form: Adverse Events (2)

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[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|------------------------|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:26:40 |
| User entered 'Yes (Y)' | Jessie Downs (b) (4) | 29 Jan 2021 20:02:31 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:17

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|-----------------------|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:26:40 |
| User entered 'No (N)' | Jessie Downs (b) (4) | 29 Jan 2021 20:02:31 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (2)

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|-----------------------|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:26:40 |
| User entered 'No (N)' | Jessie Downs (b) (4) | 29 Jan 2021 20:02:31 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:26:40 |
| User entered '23 Jan 2021' | Jessie Downs (b) (4) | 29 Jan 2021 20:02:31 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:17

Start time (00:00-23:59)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:26:40 |
| User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System). | System | 29 Jan 2021 20:11:04 |
| User entered empty; reason for change Data Entry Error | Jessie Downs (b) (4) | 29 Jan 2021 20:11:04 |
| User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System). | System | 29 Jan 2021 20:02:31 |
| User entered '12:30' | Jessie Downs (b) (4) | 29 Jan 2021 20:02:31 |

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Folder: Adverse Events

Form: Adverse Events (2)

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[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered empty. | System | 29 Jan 2021 20:11:04 |
| User entered '23 Jan 2021 12:30' | System | 29 Jan 2021 20:02:31 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:17

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---|-----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:26:40 |
| User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety). | (b) (4), (b) (6) | 08 Apr 2021 14:26:29 |
| Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'end date added.' (Site from Safety). | Jessie Downs (b) (4) (b) (4) | 08 Apr 2021 13:32:55 |
| User entered 'No (N)' reason for change: Data Entry Error | Mariete Rendon (b) (4) (b) (4) | 07 Apr 2021 16:36:59 |
| User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety). | (b) (4), (b) (6) | 09 Mar 2021 19:07:44 |
| User entered 'Yes (Y)' | Jessie Downs (b) (4) (b) (4) | 29 Jan 2021 20:02:31 |

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Folder: Adverse Events

Form: Adverse Events (2)

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If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|-----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:26:40 |
| User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety). | (b) (4), (b) (6) | 08 Apr 2021 14:26:36 |
| Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'end date added.' (Site from Safety). | Jessie Downs (b) (4) (b) (4) | 08 Apr 2021 13:33:15 |
| User entered '1 Mar 2021' reason for change: Data Entry Error | Mariete Rendon (b) (4) (b) (4) | 07 Apr 2021 16:36:59 |
| User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety). | (b) (4), (b) (6) | 01 Mar 2021 19:37:37 |
| User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety). | (b) (4), (b) (6) | 01 Mar 2021 19:37:37 |
| Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'pending' (Site from Safety). | Jessie Downs (b) (4) (b) (4) | 26 Feb 2021 21:51:18 |
| User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety). | (b) (4), (b) (6) | 08 Feb 2021 15:08:44 |
| User entered empty. | Jessie Downs (b) (4) (b) (4) | 29 Jan 2021 20:02:31 |

US3172224

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:17

End time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:26:40 |
| User entered empty. | Jessie Downs (b) (4) | 29 Jan 2021 20:02:31 |
| | (b) (4) | |

US3172224

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:17

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 29 Jan 2021 20:02:31 |

US3172224

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:17

[Severity](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:26:40 |
| User entered 'Grade 3/Severe (Grade 3/Severe)' | Jessie Downs (b) (4) (b) (4) | 29 Jan 2021 20:02:31 |

US3172224

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:17

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:26:40 |
| 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 | 29 Jan 2021 20:11:04 |
| 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 | 29 Jan 2021 20:02:31 |
| User entered 'Yes (Y)' | Jessie Downs (b) (4) (b) (4) | 29 Jan 2021 20:02:31 |

US3172224

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:17

[Death](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:26:40 |
| User entered '0' | Jessie Downs (b) (4) | 29 Jan 2021 20:02:31 |
| | (b) (4) | |

US3172224

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:17

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:26:40 |
| User entered '0' | Jessie Downs (b) (4) | 29 Jan 2021 20:02:31 |
| | (b) (4) | |

US3172224

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:17

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:26:40 |
| User closed query 'Requires inpatient or prolongation System of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System). | | 29 Jan 2021 20:38:54 |
| Query 'Requires inpatient or prolongation of existing System Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered by data change (Site from System). | | 29 Jan 2021 20:38:54 |
| User closed query 'Requires inpatient or prolongation System of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System). | | 29 Jan 2021 20:11:04 |
| Query 'Requires inpatient or prolongation of existing System Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System). | | 29 Jan 2021 20:11:04 |
| User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System). | System | 29 Jan 2021 20:11:04 |
| User entered '1' reason for change: Data Entry Error | Jessie Downs (b) (4) | 29 Jan 2021 20:11:04 |
| User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System). | (b) (4) System | 29 Jan 2021 20:02:31 |
| User entered '0' | Jessie Downs (b) (4) (b) (4) | 29 Jan 2021 20:02:31 |

US3172224

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:17

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:26:40 |
| User entered '23 Jan 2021' | Jessie Downs (b) (4) | 29 Jan 2021 20:02:31 |
| | (b) (4) | |

US3172224

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:17

Hospital Discharge Date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:26:40 |
| User closed query 'PVQuery: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results 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) | 01 Mar 2021 19:38:58 |
| Query 'PVQuery: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results 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 'pending' (Site from Safety). | Jessie Downs (b) (4) (b) (4) | 26 Feb 2021 21:51:33 |
| User opened query 'PVQuery: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results 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) | 08 Feb 2021 15:12:25 |
| User entered '27 Jan 2021' | Jessie Downs (b) (4) (b) (4) | 29 Jan 2021 20:02:31 |

US3172224

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:17

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:26:40 |
| User entered 'No (N)' reason for change: Data Entry Error | Jessie Downs (b) (4) | 29 Jan 2021 20:38:54 |
| User entered empty. | Jessie Downs (b) (4) | 29 Jan 2021 20:02:31 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:17

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:26:40 |
| User entered empty. | Jessie Downs (b) (4) | 29 Jan 2021 20:02:31 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:17

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:26:40 |
| User entered '0' | Jessie Downs (b) (4) | 29 Jan 2021 20:02:31 |
| | (b) (4) | |

US3172224

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:17

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:26:40 |
| User entered '0' | Jessie Downs (b) (4) | 29 Jan 2021 20:02:31 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:17

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:26:40 |
| User entered '0' | Jessie Downs (b) (4) | 29 Jan 2021 20:02:31 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:17

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:26:40 |
| User entered 'Not Related (NOT RELATED)' | Jessie Downs (b) (4) (b) (4) | 29 Jan 2021 20:02:31 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:17

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:26:40 |
| User entered 'Not Related (NOT RELATED)' | Jessie Downs (b) (4) (b) (4) | 29 Jan 2021 20:02:31 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:17

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:26:40 |
| User entered 'Not Applicable (NOT APPLICABLE)' | Jessie Downs (b) (4) | 29 Jan 2021 20:02:31 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:17

[None](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:26:40 |
| User entered '0' | Jessie Downs (b) (4) | 29 Jan 2021 20:02:31 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:17

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:26:40 |
| User entered 'I' | Jessie Downs (b) (4) | 29 Jan 2021 20:02:31 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:17

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:26:40 |
| User closed query 'Per DM CLR: Other Action Taken = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM). | (b) (4), (b) (6) | 05 Mar 2021 06:46:18 |
| Query 'Per DM CLR: Other Action Taken = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' answered with 'pending' (Site from DM). | Jessie Downs (b) (4) (b) (4) | 26 Feb 2021 21:51:47 |
| User opened query 'Per DM CLR: Other Action Taken = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM). | (b) (4), (b) (6) | 19 Feb 2021 05:28:11 |
| User entered 'I' | Jessie Downs (b) (4) (b) (4) | 29 Jan 2021 20:02:31 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:17

[Outcome](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:26:40 |
| Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' canceled (Site from Safety). | (b) (4), (b) (6) | 13 Apr 2021 12:30:15 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error | Mariete Rendon (b) (4) (b) (4) | 07 Apr 2021 16:36:59 |
| User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety). | (b) (4), (b) (6) | 01 Mar 2021 19:39:22 |
| User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety). | (b) (4), (b) (6) | 01 Mar 2021 19:39:22 |
| Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' answered with 'pending' (Site from Safety). | Jessie Downs (b) (4) (b) (4) | 26 Feb 2021 21:52:00 |
| User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety). | (b) (4), (b) (6) | 08 Feb 2021 15:09:09 |
| User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' | Jessie Downs (b) (4) (b) (4) | 29 Jan 2021 20:02:31 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:17

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:26:40 |
| User entered empty. | Jessie Downs (b) (4) | 29 Jan 2021 20:02:31 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:17

[Narrative](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| DataPoint Un-verified. | (b) (4), (b) (6) | 19 Apr 2021 16:26:43 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:26:40 |
| User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety). | (b) (4), (b) (6) | 01 Mar 2021 19:39:29 |
| User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety). | (b) (4), (b) (6) | 01 Mar 2021 19:39:29 |
| User opened query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results 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) | 01 Mar 2021 19:39:07 |
| User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety). | (b) (4), (b) (6) | 01 Mar 2021 19:39:02 |
| Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'pending' (Site from Safety). | Jessie Downs (b) (4) (b) (4) | 26 Feb 2021 21:52:31 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:17

[Narrative](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'pending' (Site from Safety). | Jessie Downs (b) (4) (b) (4) | 26 Feb 2021 21:52:14 |
| User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety). | (b) (4), (b) (6) | 08 Feb 2021 15:10:10 |
| User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety). | (b) (4), (b) (6) | 08 Feb 2021 15:09:17 |
| User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System). | System | 29 Jan 2021 20:11:04 |
| Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System). | System | 29 Jan 2021 20:11:04 |
| User entered 'Right rib cage multiple fractures secondary to a motor vehicle accident on 1/23/2021 requiring hospitalization due to multiple trauma and Hemopneumothorax resolved with thoracostomy (chest tube) multiple abrasions right knee, both elbow, abdomen, hips, and forehead without clinically significance. He was discharged home on 1/27/2021 on a stable condition with oral meds for pain and swelling. Will monitor.' reason for change: Data Entry Error | Jessie Downs (b) (4) (b) (4) | 29 Jan 2021 20:11:04 |
| User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System). | System | 29 Jan 2021 20:02:31 |
| User entered empty. | Jessie Downs (b) (4) (b) (4) | 29 Jan 2021 20:02:31 |

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:17

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 29 Jan 2021 20:02:31 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:17

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 29 Jan 2021 20:02:31 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:17

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '0' | System | 29 Jan 2021 20:38:54 |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:17

[Adverse event](#)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:26:40 |
| User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Injuries NEC, HLT: Skin injuries NEC, PT: Skin abrasion, LLT: Skin abrasion - version MedDRA\23.0. | Coder Import (b) (4) | 08 Apr 2021 14:45:54 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0. | (b) (4) | 08 Apr 2021 14:45:54 |
| Data point term sent to Coder | System | 08 Apr 2021 13:35:12 |
| User closed query 'CDM Coding, please split the term (MULTIPLE SKIN ABRASIONS - SECONDARY TO A CAR ACCIDENT) into separate records, as 'MULTIPLE SKIN ABRASIONS' and 'CAR ACCIDENT' reporting each term separately with all relevant information e.g. start and stop dates etc. ' (Site from System). | System | 08 Apr 2021 13:34:58 |
| Query 'CDM Coding, please split the term (MULTIPLE SKIN ABRASIONS - SECONDARY TO A CAR ACCIDENT) into separate records, as 'MULTIPLE SKIN ABRASIONS' and 'CAR ACCIDENT' reporting each term separately with all relevant information e.g. start and stop dates etc. ' answered with 'Data was updated.' (Site from System). | Jessie Downs (b) (4) | 08 Apr 2021 13:34:58 |
| User entered 'MULTIPLE SKIN ABRASIONS' reason for change: Data Entry Error | (b) (4) | 08 Apr 2021 13:34:24 |
| Query 'Requery, Please separate the accident from the Injury. 1 per line' canceled (Site from Coder). | (b) (4), (b) (6) | 30 Mar 2021 14:25:41 |
| User opened query 'CDM Coding, please split the term (MULTIPLE SKIN ABRASIONS - SECONDARY TO A CAR ACCIDENT) into separate records, as 'MULTIPLE SKIN ABRASIONS' and 'CAR ACCIDENT' reporting each term separately with all relevant information e.g. start and stop dates etc. ' (Site from System). | Coder Import (b) (4) | 19 Mar 2021 07:20:00 |
| User opened query 'Requery, Please separate the accident from the Injury. 1 per line' (Site from Coder). | (b) (4), (b) (6) | 28 Feb 2021 13:10:55 |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:17

[Adverse event](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User closed query 'For coding purposes, please split MULTIPLE SKIN ABRASIONS - SECONDARY TO A CAR ACCIDENT into separate entries. 1. MULTIPLE SKIN ABRASIONS - [SECONDARY TO A CAR ACCIDENT] and 2. CAR ACCIDENT' (Site from Coder). | (b) (4), (b) (6) | 28 Feb 2021 13:10:55 |
| Query 'For coding purposes, please split MULTIPLE SKIN ABRASIONS - SECONDARY TO A CAR ACCIDENT into separate entries. 1. MULTIPLE SKIN ABRASIONS - [SECONDARY TO A CAR ACCIDENT] and 2. CAR ACCIDENT' answered with 'data confirmed as entered. ' (Site from Coder). | Jessie Downs (b) (4) | 26 Feb 2021 21:53:03 |
| User opened query 'For coding purposes, please split MULTIPLE SKIN ABRASIONS - SECONDARY TO A CAR ACCIDENT into separate entries. 1. MULTIPLE SKIN ABRASIONS - [SECONDARY TO A CAR ACCIDENT] and 2. CAR ACCIDENT' (Site from Coder). | (b) (4), (b) (6) | 02 Feb 2021 19:14:41 |
| Data point term sent to Coder | System | 29 Jan 2021 20:17:16 |
| User entered 'Multiple skin abrasions - secondary to a car accident' | Jessie Downs (b) (4) | 29 Jan 2021 20:16:50 |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:17

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|------------------------|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:26:40 |
| User entered 'Yes (Y)' | Jessie Downs (b) (4) | 29 Jan 2021 20:16:50 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:17

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|-----------------------|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:26:40 |
| User entered 'No (N)' | Jessie Downs (b) (4) | 29 Jan 2021 20:16:50 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:17

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|-----------------------|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:26:40 |
| User entered 'No (N)' | Jessie Downs (b) (4) | 29 Jan 2021 20:16:50 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:17

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:26:40 |
| User entered '23 Jan 2021' | Jessie Downs (b) (4) | 29 Jan 2021 20:16:50 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:17

Start time (00:00-23:59)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:26:40 |
| User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System). | System | 29 Jan 2021 20:16:58 |
| User entered empty; reason for change Data Entry Error | Jessie Downs (b) (4) | 29 Jan 2021 20:16:58 |
| User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System). | System | 29 Jan 2021 20:16:50 |
| User entered '12:30' | Jessie Downs (b) (4) | 29 Jan 2021 20:16:50 |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:17

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered empty. | System | 29 Jan 2021 20:16:58 |
| User entered '23 Jan 2021 12:30' | System | 29 Jan 2021 20:16:50 |

US3172224

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:17

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:26:40 |
| User entered 'No (N)' reason for change: Data Entry Error | Jessie Downs (b) (4) | 16 Apr 2021 16:25:51 |
| User entered 'Yes (Y)' | Jessie Downs (b) (4) | 29 Jan 2021 20:16:50 |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:17

If not Ongoing, end date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:26:40 |
| User entered '03 Mar 2021' reason for change: Data Entry Error | Jessie Downs (b) (4) | 16 Apr 2021 16:25:51 |
| User entered empty. | Jessie Downs (b) (4) | 29 Jan 2021 20:16:50 |

US3172224

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:17

End time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:26:40 |
| User entered empty. | Jessie Downs (b) (4) | 29 Jan 2021 20:16:50 |
| | (b) (4) | |

US3172224

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:17

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 29 Jan 2021 20:16:50 |

US3172224

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:17

[Severity](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:26:40 |
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' | Jessie Downs (b) (4) | 29 Jan 2021 20:16:50 |
| | (b) (4) | |

US3172224

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:17

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|-----------------------|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:26:40 |
| User entered 'No (N)' | Jessie Downs (b) (4) | 29 Jan 2021 20:16:50 |
| | (b) (4) | |

US3172224

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:17

[Death](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:26:40 |
| User entered '0' | Jessie Downs (b) (4) | 29 Jan 2021 20:16:50 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:17

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:26:40 |
| User entered '0' | Jessie Downs (b) (4) | 29 Jan 2021 20:16:50 |
| | (b) (4) | |

US3172224

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:17

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:26:40 |
| User entered '0' | Jessie Downs (b) (4) | 29 Jan 2021 20:16:50 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:17

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:26:40 |
| User entered empty. | Jessie Downs (b) (4) | 29 Jan 2021 20:16:50 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:17

Hospital Discharge Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:26:40 |
| User entered empty. | Jessie Downs (b) (4) | 29 Jan 2021 20:16:50 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:17

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:26:40 |
| User entered empty. | Jessie Downs (b) (4) | 29 Jan 2021 20:16:50 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:17

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:26:40 |
| User entered empty. | Jessie Downs (b) (4) | 29 Jan 2021 20:16:50 |
| | (b) (4) | |

US3172224

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:17

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:26:40 |
| User entered '0' | Jessie Downs (b) (4) | 29 Jan 2021 20:16:50 |
| | (b) (4) | |

US3172224

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:17

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:26:40 |
| User entered '0' | Jessie Downs (b) (4) | 29 Jan 2021 20:16:50 |
| | (b) (4) | |

US3172224

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:17

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:26:40 |
| User entered '0' | Jessie Downs (b) (4) | 29 Jan 2021 20:16:50 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:17

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:26:40 |
| User entered 'Not Related (NOT RELATED)' | Jessie Downs (b) (4) (b) (4) | 29 Jan 2021 20:16:50 |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:17

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:26:40 |
| User entered 'Not Related (NOT RELATED)' | Jessie Downs (b) (4) | 29 Jan 2021 20:16:50 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:17

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:26:40 |
| User entered 'Not Applicable (NOT APPLICABLE)' | Jessie Downs (b) (4) | 29 Jan 2021 20:16:50 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:17

[None](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:26:40 |
| User entered '1' | Jessie Downs (b) (4) | 29 Jan 2021 20:16:50 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:17

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:26:40 |
| User entered '0' | Jessie Downs (b) (4) | 29 Jan 2021 20:16:50 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:17

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:26:40 |
| User entered '0' | Jessie Downs (b) (4) | 29 Jan 2021 20:16:50 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:17

[Outcome](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:26:40 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error | Jessie Downs (b) (4) | 16 Apr 2021 16:25:51 |
| User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' | Jessie Downs (b) (4) | 29 Jan 2021 20:16:50 |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:17

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:26:40 |
| User entered empty. | Jessie Downs (b) (4) | 29 Jan 2021 20:16:50 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:17

[Narrative](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:26:40 |
| User entered empty. | Jessie Downs (b) (4) | 29 Jan 2021 20:16:50 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:17

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '0' | System | 29 Jan 2021 20:16:50 |

US3172224

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:17

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 29 Jan 2021 20:16:50 |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:33:17

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 10:55:08 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'Yes (Y)' | Mariete Rendon (b) (4) (b) (4) | 19 Aug 2020 21:15:19 |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:33:17

Name of Medication

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:03:28 |
| | | |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| | | |
| User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 19 Aug 2020 21:17:13 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 19 Aug 2020 21:17:13 |
| | (b) (4) | |
| Data point term sent to Coder | System | 19 Aug 2020 21:16:16 |
| User entered 'IBUPROFEN' | Mariete Rendon (b) (4) | 19 Aug 2020 21:15:55 |
| | (b) (4) | |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:33:17

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:03:28 |
| | | |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| | | |
| User entered 'No (N)' | Mariete Rendon (b) (4) | 19 Aug 2020 21:15:55 |
| | (b) (4) | |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:33:17

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:03:28 |
| | | |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| | | |
| User entered 'BACK PAIN' | Mariete Rendon (b) (4) | 19 Aug 2020 21:15:55 |
| | (b) (4) | |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:33:17

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:03:28 |
| | | |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| | | |
| User entered '600' | Mariete Rendon (b) (4) | 19 Aug 2020 21:15:55 |
| | (b) (4) | |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:33:17

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:03:28 |
| | | |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| | | |
| User entered 'mg (mg)' | Mariete Rendon (b) (4) | 19 Aug 2020 21:15:55 |
| | (b) (4) | |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:33:17

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:03:28 |
| | | |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| | | |
| User entered empty. | Mariete Rendon (b) (4) | 19 Aug 2020 21:15:55 |
| | (b) (4) | |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:33:17

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:03:28 |
| | | |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| | | |
| User entered 'once daily (QD)' | Mariete Rendon (b) (4) | 19 Aug 2020 21:15:55 |
| | (b) (4) | |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:33:17

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:03:28 |
| | | |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| User entered empty. | Mariete Rendon (b) (4) | 19 Aug 2020 21:15:55 |
| | (b) (4) | |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:33:17

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:03:28 |
| | | |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| | | |
| User entered 'Oral (ORAL)' | Mariete Rendon (b) (4) | 19 Aug 2020 21:15:55 |
| | (b) (4) | |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:33:17

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:03:28 |
| | | |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| User entered empty. | Mariete Rendon (b) (4) | 19 Aug 2020 21:15:55 |
| | (b) (4) | |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:33:17

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:03:28 |
| | | |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| | | |
| Amendment Manager: Query closed during migration process because the edit check no longer exists in target version. | System | 21 Aug 2020 05:41:05 |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | System | 19 Aug 2020 21:15:55 |
| User entered 'UN UNK 1995' | Mariete Rendon (b) (4) | 19 Aug 2020 21:15:55 |
| | (b) (4) | |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:33:17

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:03:28 |
| | | |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| | | |
| User entered '0' | Mariete Rendon (b) (4) | 19 Aug 2020 21:15:55 |
| | (b) (4) | |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:33:17

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:03:28 |
| | | |
| User signature succeeded. | Mark Kutner (b) (4) | 22 Apr 2021 16:25:33 |
| | (b) (4) | |
| | | |
| Signature has been broken. | Jessie Downs (b) (4) | 22 Mar 2021 18:59:55 |
| | (b) (4) | |
| User entered 'No (N)' reason for change: Data Entry Error | Jessie Downs (b) (4) | 22 Mar 2021 18:59:55 |
| | (b) (4) | |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| | | |
| User entered 'Yes (Y)' | Mariete Rendon (b) (4) | 19 Aug 2020 21:15:55 |
| | (b) (4) | |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:33:17

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:03:28 |
| | | |
| User signature succeeded. | Mark Kutner (b) (4) | 22 Apr 2021 16:25:33 |
| | (b) (4) | |
| | | |
| Signature has been broken. | Jessie Downs (b) (4) | 22 Mar 2021 18:59:55 |
| | (b) (4) | |
| User entered '19 Aug 2020' reason for change: Data Entry Error | Jessie Downs (b) (4) | 22 Mar 2021 18:59:55 |
| | (b) (4) | |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| | | |
| User entered empty. | Mariete Rendon (b) (4) | 19 Aug 2020 21:15:55 |
| | (b) (4) | |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:33:17

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:03:28 |
| | | |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| | | |
| User entered 'No (N)' | Mariete Rendon (b) (4) | 19 Aug 2020 21:15:55 |
| | (b) (4) | |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:33:17

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:03:28 |
| | | |
| User entered '1' | System | 19 Aug 2020 21:15:55 |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:33:17

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:03:28 |
| | | |
| User entered '1' | System | 19 Aug 2020 21:15:55 |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:33:17

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:03:28 |
| | | |
| User entered '804 (804)' | System | 19 Aug 2020 21:15:55 |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:33:17

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 19 Aug 2020 21:18:15 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 19 Aug 2020 21:18:15 |
| | (b) (4) | |
| Data point term sent to Coder | System | 19 Aug 2020 21:17:17 |
| User entered 'FAMOTIDINE' | Mariete Rendon (b) (4) | 19 Aug 2020 21:16:32 |
| | (b) (4) | |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:33:17

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'No (N)' | Mariete Rendon (b) (4) (b) (4) | 19 Aug 2020 21:16:32 |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:33:17

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'HEARTBURN' | Mariete Rendon (b) (4) (b) (4) | 19 Aug 2020 21:16:32 |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:33:17

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered '10' | Mariete Rendon (b) (4) (b) (4) | 19 Aug 2020 21:16:32 |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:33:17

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'mg (mg)' | Mariete Rendon (b) (4) (b) (4) | 19 Aug 2020 21:16:32 |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:33:17

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered empty. | Mariete Rendon (b) (4) (b) (4) | 19 Aug 2020 21:16:32 |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:33:17

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'as needed (PRN)' | Mariete Rendon (b) (4) (b) (4) | 19 Aug 2020 21:16:32 |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:33:17

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered empty. | Mariete Rendon (b) (4) (b) (4) | 19 Aug 2020 21:16:32 |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:33:17

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'Oral (ORAL)' | Mariete Rendon (b) (4) (b) (4) | 19 Aug 2020 21:16:32 |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:33:17

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered empty. | Mariete Rendon (b) (4) (b) (4) | 19 Aug 2020 21:16:32 |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:33:17

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| Amendment Manager: Query closed during migration process because the edit check no longer exists in target version. | System | 21 Aug 2020 05:41:05 |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | System | 19 Aug 2020 21:16:32 |
| User entered 'UN UNK 2010' | Mariete Rendon (b) (4) | 19 Aug 2020 21:16:32 |
| | (b) (4) | |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:33:17

Start date completely unknown

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered '0' | Mariete Rendon (b) (4) (b) (4) | 19 Aug 2020 21:16:32 |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:33:17

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'Yes (Y)' | Mariete Rendon (b) (4) (b) (4) | 19 Aug 2020 21:16:32 |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:33:17

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered empty. | Mariete Rendon (b) (4) (b) (4) | 19 Aug 2020 21:16:32 |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:33:17

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'No (N)' | Mariete Rendon (b) (4) (b) (4) | 19 Aug 2020 21:16:32 |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:33:17

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 19 Aug 2020 21:16:32 |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:33:17

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 19 Aug 2020 21:16:32 |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:33:17

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 19 Aug 2020 21:16:32 |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:33:17

Name of Medication

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:05:58 |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| User closed query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med IBUPROFEN, #1 within this timeframe (UN UNK 1995 - ONGOING). Please consider updating dates so there is no overlap or delete if this is a duplicate. Update Con Med eCRF as appropriate. Otherwise, provide a comment.' (Site from DM). | (b) (4), (b) (6) | 26 Oct 2020 16:59:49 |
| Query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med IBUPROFEN, #1 within this timeframe (UN UNK 1995 - ONGOING). Please consider updating dates so there is no overlap or delete if this is a duplicate. Update Con Med eCRF as appropriate. Otherwise, provide a comment.' answered with 'Data was updated ' (Site from DM). | Jessie Downs (b) (4) | 16 Oct 2020 20:43:04 |
| User opened query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med IBUPROFEN, #1 within this timeframe (UN UNK 1995 - ONGOING). Please consider updating dates so there is no overlap or delete if this is a duplicate. Update Con Med eCRF as appropriate. Otherwise, provide a comment.' (Site from DM). | (b) (4), (b) (6) | 15 Oct 2020 19:34:45 |
| User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\202003. | Coder Import (b) (4) | 27 Sep 2020 09:28:43 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003. | Coder Import (b) (4) | 27 Sep 2020 09:28:43 |
| Data point term sent to Coder | System | 25 Sep 2020 17:19:23 |
| User entered 'Ibuprofen' | Mariete Rendon (b) (4) | 25 Sep 2020 17:18:26 |

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EAB) (1725)

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US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:33:17

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:05:58 |
| | | |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| | | |
| User entered 'No (N)' | Mariete Rendon (b) (4) | 25 Sep 2020 17:18:26 |
| | (b) (4) | |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:33:17

[Indication](#)

| Audit | User | Time (GMT) |
|-------------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:05:58 |
| | | |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| | | |
| User entered 'historical back pain' | Mariete Rendon (b) (4) | 25 Sep 2020 17:18:26 |
| | (b) (4) | |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:33:17

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:05:58 |
| | | |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| | | |
| User entered '600' | Mariete Rendon (b) (4) | 25 Sep 2020 17:18:26 |
| | (b) (4) | |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:33:17

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:05:58 |
| | | |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| | | |
| User entered 'mg (mg)' | Mariete Rendon (b) (4) | 25 Sep 2020 17:18:26 |
| | (b) (4) | |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:33:17

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:05:58 |
| | | |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| | | |
| User entered empty. | Mariete Rendon (b) (4) | 25 Sep 2020 17:18:26 |
| | (b) (4) | |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:33:17

[Frequency](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:05:58 |
| | | |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| | | |
| User closed query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System). | System | 16 Oct 2020 20:43:55 |
| Query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' answered by data change (Site from System). | System | 16 Oct 2020 20:43:55 |
| User entered 'unknown (UNKNOWN)' reason for change: Data Entry Error | Jessie Downs (b) (4) | 16 Oct 2020 20:43:55 |
| | (b) (4) | |
| User opened query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System). | System | 16 Oct 2020 20:42:46 |
| User entered 'once (ONCE)' | Mariete Rendon (b) (4) | 25 Sep 2020 17:18:26 |
| | (b) (4) | |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:33:17

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:05:58 |
| | | |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| | | |
| User entered empty. | Mariete Rendon (b) (4) | 25 Sep 2020 17:18:26 |
| | (b) (4) | |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:33:17

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:05:58 |
| | | |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| | | |
| User entered 'Oral (ORAL)' | Mariete Rendon (b) (4) | 25 Sep 2020 17:18:26 |
| | (b) (4) | |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:33:17

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:05:58 |
| | | |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| | | |
| User entered empty. | Mariete Rendon (b) (4) | 25 Sep 2020 17:18:26 |
| | (b) (4) | |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:33:17

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:05:58 |
| | | |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| | | |
| User entered 'UN UNK 1995' reason for change: | Jessie Downs (b) (4) | 16 Oct 2020 20:42:46 |
| Data Entry Error | (b) (4) | |
| User entered '22 Sep 2020' | Mariete Rendon (b) (4) | 25 Sep 2020 17:18:26 |
| | (b) (4) | |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:33:17

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:05:58 |
| | | |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| | | |
| User entered '0' | Mariete Rendon (b) (4) | 25 Sep 2020 17:18:26 |
| | (b) (4) | |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:33:17

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:05:58 |
| | | |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| | | |
| User entered 'No (N)' | Mariete Rendon (b) (4) | 25 Sep 2020 17:18:26 |
| | (b) (4) | |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:33:17

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:05:58 |
| | | |
| User signature succeeded. | Mark Kutner (b) (4) | 22 Apr 2021 16:25:33 |
| | (b) (4) | |
| | | |
| Signature has been broken. | Jessie Downs (b) (4) | 22 Mar 2021 18:59:16 |
| | (b) (4) | |
| User entered '16 Oct 2020' reason for change: Data Entry Error | Jessie Downs (b) (4) | 22 Mar 2021 18:59:16 |
| | (b) (4) | |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| | | |
| User entered '22 Sep 2020' | Mariete Rendon (b) (4) | 25 Sep 2020 17:18:26 |
| | (b) (4) | |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:33:17

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:05:58 |
| | | |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| | | |
| User entered 'No (N)' | Mariete Rendon (b) (4) | 25 Sep 2020 17:18:26 |
| | (b) (4) | |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:33:17

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:05:58 |
| | | |
| User entered empty. | System | 25 Sep 2020 17:18:26 |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:33:17

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:05:58 |
| | | |
| User entered empty. | System | 25 Sep 2020 17:18:26 |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:33:17

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:05:58 |
| | | |
| User entered empty. | System | 25 Sep 2020 17:18:26 |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:33:17

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:04:31 |
| | | |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 01 Feb 2021 15:37:29 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 01 Feb 2021 15:37:29 |
| | (b) (4) | |
| Data point term sent to Coder | System | 29 Jan 2021 20:24:21 |
| User entered 'oxycodone' | Jessie Downs (b) (4) | 29 Jan 2021 20:23:35 |
| | (b) (4) | |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:33:17

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:04:31 |
| | | |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| | | |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 29 Jan 2021 20:30:03 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 29 Jan 2021 20:30:03 |
| User entered 'No (N)' reason for change: Data Entry Error | Jessie Downs (b) (4) | 29 Jan 2021 20:30:03 |
| | (b) (4) | |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 29 Jan 2021 20:23:35 |
| User entered empty. | Jessie Downs (b) (4) | 29 Jan 2021 20:23:35 |
| | (b) (4) | |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:33:17

[Indication](#)

| Audit | User | Time (GMT) |
|------------------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:04:31 |
| | | |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| | | |
| User entered 'right rib cage pain' | Jessie Downs (b) (4) | 29 Jan 2021 20:23:35 |
| | (b) (4) | |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:33:17

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:04:31 |
| | | |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| | | |
| User entered '10' | Jessie Downs (b) (4) | 29 Jan 2021 20:23:35 |
| | (b) (4) | |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:33:17

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:04:31 |
| | | |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| | | |
| User entered 'mg (mg)' | Jessie Downs (b) (4) | 29 Jan 2021 20:23:35 |
| | (b) (4) | |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:33:17

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:04:31 |
| | | |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| | | |
| User entered empty. | Jessie Downs (b) (4) | 29 Jan 2021 20:23:35 |
| | (b) (4) | |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:33:17

[Frequency](#)

| Audit | User | Time (GMT) |
|------------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:04:31 |
| | | |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| | | |
| User entered 'other (OTHER)' | Jessie Downs (b) (4) | 29 Jan 2021 20:23:35 |
| | (b) (4) | |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:33:17

If frequency is Other, specify

| Audit | User | Time (GMT) |
|------------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:04:31 |
| | | |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| | | |
| User entered 'every 6 hours' | Jessie Downs (b) (4) | 29 Jan 2021 20:23:35 |
| | (b) (4) | |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:33:17

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:04:31 |
| | | |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| | | |
| User entered 'Oral (ORAL)' | Jessie Downs (b) (4) | 29 Jan 2021 20:23:35 |
| | (b) (4) | |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:33:17

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:04:31 |
| | | |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| | | |
| User entered empty. | Jessie Downs (b) (4) | 29 Jan 2021 20:23:35 |
| | (b) (4) | |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:33:17

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:04:31 |
| | | |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| | | |
| User entered '23 Jan 2021' | Jessie Downs (b) (4) | 29 Jan 2021 20:23:35 |
| | (b) (4) | |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:33:17

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:04:31 |
| | | |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| | | |
| User entered '0' | Jessie Downs (b) (4) | 29 Jan 2021 20:23:35 |
| | (b) (4) | |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:33:17

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:04:31 |
| | | |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| | | |
| User entered 'No (N)' | Jessie Downs (b) (4) | 29 Jan 2021 20:23:35 |
| | (b) (4) | |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:33:17

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:04:31 |
| | | |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| | | |
| User entered '27 Jan 2021' | Jessie Downs (b) (4) | 29 Jan 2021 20:23:35 |
| | (b) (4) | |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:33:17

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:04:31 |
| | | |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| | | |
| User entered 'No (N)' | Jessie Downs (b) (4) | 29 Jan 2021 20:23:35 |
| | (b) (4) | |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:33:17

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:04:31 |
| | | |
| User entered empty. | System | 29 Jan 2021 20:23:35 |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:33:17

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:04:31 |
| | | |
| User entered empty. | System | 29 Jan 2021 20:23:35 |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:33:17

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:04:31 |
| | | |
| User entered empty. | System | 29 Jan 2021 20:23:35 |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:33:17

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:04:33 |
| | | |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: KETOROLAC TROMETHAMINE, PRODUCTSYNONYM: TORADOL - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 01 Feb 2021 15:43:29 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 01 Feb 2021 15:43:29 |
| | (b) (4) | |
| Data point term sent to Coder | System | 29 Jan 2021 20:27:25 |
| User entered 'toradol' | Jessie Downs (b) (4) | 29 Jan 2021 20:26:31 |
| | (b) (4) | |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:33:17

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:04:33 |
| | | |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| | | |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 29 Jan 2021 20:26:56 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 29 Jan 2021 20:26:56 |
| User entered 'No (N)' reason for change: Data Entry Error | Jessie Downs (b) (4) | 29 Jan 2021 20:26:56 |
| | (b) (4) | |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 29 Jan 2021 20:26:31 |
| User entered empty. | Jessie Downs (b) (4) | 29 Jan 2021 20:26:31 |
| | (b) (4) | |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:33:17

[Indication](#)

| Audit | User | Time (GMT) |
|------------------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:04:33 |
| | | |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| | | |
| User entered 'right rib cage pain' | Jessie Downs (b) (4) | 29 Jan 2021 20:26:31 |
| | (b) (4) | |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:33:17

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:04:33 |
| | | |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| | | |
| User entered '15' | Jessie Downs (b) (4) | 29 Jan 2021 20:26:31 |
| | (b) (4) | |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:33:17

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:04:33 |
| | | |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| | | |
| User entered 'mg (mg)' | Jessie Downs (b) (4) | 29 Jan 2021 20:26:31 |
| | (b) (4) | |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:33:17

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:04:33 |
| | | |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| | | |
| User entered empty. | Jessie Downs (b) (4) | 29 Jan 2021 20:26:31 |
| | (b) (4) | |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:33:17

[Frequency](#)

| Audit | User | Time (GMT) |
|------------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:04:33 |
| | | |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| | | |
| User entered 'other (OTHER)' | Jessie Downs (b) (4) | 29 Jan 2021 20:26:31 |
| | (b) (4) | |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:33:17

If frequency is Other, specify

| Audit | User | Time (GMT) |
|------------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:04:33 |
| | | |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| | | |
| User entered 'every 6 hours' | Jessie Downs (b) (4) | 29 Jan 2021 20:26:31 |
| | (b) (4) | |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:33:17

[Route of administration](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:04:33 |
| | | |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| | | |
| User entered 'Intravenous (INTRAVENOUS)' | Jessie Downs (b) (4) | 29 Jan 2021 20:26:31 |
| | (b) (4) | |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:33:17

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:04:33 |
| | | |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| | | |
| User entered empty. | Jessie Downs (b) (4) | 29 Jan 2021 20:26:31 |
| | (b) (4) | |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:33:17

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:04:33 |
| | | |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| | | |
| User entered '23 Jan 2021' | Jessie Downs (b) (4) | 29 Jan 2021 20:26:31 |
| | (b) (4) | |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:33:17

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:04:33 |
| | | |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| | | |
| User entered '0' | Jessie Downs (b) (4) | 29 Jan 2021 20:26:31 |
| | (b) (4) | |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:33:17

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:04:33 |
| | | |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| | | |
| User entered 'No (N)' | Jessie Downs (b) (4) | 29 Jan 2021 20:26:31 |
| | (b) (4) | |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:33:17

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:04:33 |
| | | |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| | | |
| User entered '27 Jan 2021' | Jessie Downs (b) (4) | 29 Jan 2021 20:26:31 |
| | (b) (4) | |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:33:17

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:04:33 |
| | | |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| | | |
| User entered 'No (N)' | Jessie Downs (b) (4) | 29 Jan 2021 20:26:31 |
| | (b) (4) | |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:33:17

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:04:33 |
| | | |
| User entered empty. | System | 29 Jan 2021 20:26:31 |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:33:17

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:04:33 |
| | | |
| User entered empty. | System | 29 Jan 2021 20:26:31 |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:33:17

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:04:33 |
| | | |
| User entered empty. | System | 29 Jan 2021 20:26:31 |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:33:17

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:05:19 |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: ENOXAPARIN SODIUM, PRODUCTSYNONYM: LOVENOX [ENOXAPARIN SODIUM] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 03 Feb 2021 13:03:44 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 03 Feb 2021 13:03:44 |
| Data point term sent to Coder | System | 29 Jan 2021 20:29:31 |
| User entered 'tovenox' | Jessie Downs (b) (4) | 29 Jan 2021 20:28:32 |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:33:17

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:05:19 |
| | | |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| | | |
| User entered 'No (N)' | Jessie Downs (b) (4) | 29 Jan 2021 20:28:32 |
| | (b) (4) | |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:33:17

[Indication](#)

| Audit | User | Time (GMT) |
|------------------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:05:19 |
| | | |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| | | |
| User entered 'right rib cage pain' | Jessie Downs (b) (4) | 29 Jan 2021 20:28:32 |
| | (b) (4) | |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:33:17

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:05:19 |
| | | |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| | | |
| User entered '40' | Jessie Downs (b) (4) | 29 Jan 2021 20:28:32 |
| | (b) (4) | |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:33:17

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:05:19 |
| | | |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| | | |
| User entered 'mg (mg)' | Jessie Downs (b) (4) | 29 Jan 2021 20:28:32 |
| | (b) (4) | |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:33:17

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:05:19 |
| | | |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| | | |
| User entered empty. | Jessie Downs (b) (4) | 29 Jan 2021 20:28:32 |
| | (b) (4) | |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:33:17

[Frequency](#)

| Audit | User | Time (GMT) |
|------------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:05:19 |
| | | |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| | | |
| User entered 'other (OTHER)' | Jessie Downs (b) (4) | 29 Jan 2021 20:28:32 |
| | (b) (4) | |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:33:17

If frequency is Other, specify

| Audit | User | Time (GMT) |
|-------------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:05:19 |
| | | |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| | | |
| User entered 'every 12 hours' | Jessie Downs (b) (4) | 29 Jan 2021 20:28:32 |
| | (b) (4) | |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:33:17

[Route of administration](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:05:19 |
| | | |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| | | |
| User entered 'Subcutaneous (SUBCUTANEOUS)' | Jessie Downs (b) (4) | 29 Jan 2021 20:28:32 |
| | (b) (4) | |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:33:17

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:05:19 |
| | | |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| | | |
| User entered empty. | Jessie Downs (b) (4) | 29 Jan 2021 20:28:32 |
| | (b) (4) | |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:33:17

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:05:19 |
| | | |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| | | |
| User entered '23 Jan 2021' | Jessie Downs (b) (4) | 29 Jan 2021 20:28:32 |
| | (b) (4) | |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:33:17

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:05:19 |
| | | |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| | | |
| User entered '0' | Jessie Downs (b) (4) | 29 Jan 2021 20:28:32 |
| | (b) (4) | |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:33:17

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:05:19 |
| | | |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| | | |
| User entered 'No (N)' | Jessie Downs (b) (4) | 29 Jan 2021 20:28:32 |
| | (b) (4) | |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:33:17

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:05:19 |
| | | |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| | | |
| User entered '27 Jan 2021' | Jessie Downs (b) (4) | 29 Jan 2021 20:28:32 |
| | (b) (4) | |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:33:17

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:05:19 |
| | | |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| | | |
| User entered 'No (N)' | Jessie Downs (b) (4) | 29 Jan 2021 20:28:32 |
| | (b) (4) | |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:33:17

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:05:19 |
| | | |
| User entered empty. | System | 29 Jan 2021 20:28:32 |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:33:17

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:05:19 |
| | | |
| User entered empty. | System | 29 Jan 2021 20:28:32 |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:33:17

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:05:19 |
| | | |
| User entered empty. | System | 29 Jan 2021 20:28:32 |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:33:17

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:05:21 |
| | | |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| | | |
| 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) | 29 Jan 2021 21:33:23 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 29 Jan 2021 21:33:23 |
| | (b) (4) | |
| Data point term sent to Coder | System | 29 Jan 2021 20:30:33 |
| User entered 'gabapentin' | Jessie Downs (b) (4) | 29 Jan 2021 20:29:33 |
| | (b) (4) | |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:33:17

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:05:21 |
| | | |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| | | |
| User entered 'No (N)' | Jessie Downs (b) (4) | 29 Jan 2021 20:29:33 |
| | (b) (4) | |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:33:17

[Indication](#)

| Audit | User | Time (GMT) |
|------------------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:05:21 |
| | | |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| | | |
| User entered 'right rib cage pain' | Jessie Downs (b) (4) | 29 Jan 2021 20:29:33 |
| | (b) (4) | |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:33:17

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:05:21 |
| | | |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| | | |
| User entered '300' | Jessie Downs (b) (4) | 29 Jan 2021 20:29:33 |
| | (b) (4) | |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:33:17

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:05:21 |
| | | |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| | | |
| User entered 'mg (mg)' | Jessie Downs (b) (4) | 29 Jan 2021 20:29:33 |
| | (b) (4) | |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:33:17

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:05:21 |
| | | |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| | | |
| User entered empty. | Jessie Downs (b) (4) | 29 Jan 2021 20:29:33 |
| | (b) (4) | |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:33:17

[Frequency](#)

| Audit | User | Time (GMT) |
|------------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:05:21 |
| | | |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| | | |
| User entered 'other (OTHER)' | Jessie Downs (b) (4) | 29 Jan 2021 20:29:33 |
| | (b) (4) | |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:33:17

If frequency is Other, specify

| Audit | User | Time (GMT) |
|------------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:05:21 |
| | | |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| | | |
| User entered 'every 8 hours' | Jessie Downs (b) (4) | 29 Jan 2021 20:29:33 |
| | (b) (4) | |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:33:17

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:05:21 |
| | | |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| | | |
| User entered 'Oral (ORAL)' | Jessie Downs (b) (4) | 29 Jan 2021 20:29:33 |
| | (b) (4) | |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:33:17

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:05:21 |
| | | |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| | | |
| User entered empty. | Jessie Downs (b) (4) | 29 Jan 2021 20:29:33 |
| | (b) (4) | |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:33:17

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:05:21 |
| | | |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| | | |
| User entered '23 Jan 2021' | Jessie Downs (b) (4) | 29 Jan 2021 20:29:33 |
| | (b) (4) | |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:33:17

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:05:21 |
| | | |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| | | |
| User entered '0' | Jessie Downs (b) (4) | 29 Jan 2021 20:29:33 |
| | (b) (4) | |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:33:17

[Ongoing?](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:05:21 |
| | | |
| User signature succeeded. | Mark Kutner (b) (4) | 22 Apr 2021 16:25:33 |
| | (b) (4) | |
| Signature has been broken. | Jessie Downs (b) (4) | 22 Mar 2021 18:58:18 |
| | (b) (4) | |
| User entered 'No (N)' reason for change: Data Entry Error | Jessie Downs (b) (4) | 22 Mar 2021 18:58:18 |
| | (b) (4) | |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| | | |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Jessie Downs (b) (4) | 29 Jan 2021 20:29:45 |
| | (b) (4) | |
| User entered 'No (N)' | Jessie Downs (b) (4) | 29 Jan 2021 20:29:33 |
| | (b) (4) | |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:33:17

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:05:21 |
| | | |
| User signature succeeded. | Mark Kutner (b) (4) | 22 Apr 2021 16:25:33 |
| | (b) (4) | |
| Signature has been broken. | Jessie Downs (b) (4) | 22 Mar 2021 18:58:18 |
| | (b) (4) | |
| User entered '15 Mar 2021' reason for change: Data Entry Error | Jessie Downs (b) (4) | 22 Mar 2021 18:58:18 |
| | (b) (4) | |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| | | |
| User closed query 'Ongoing is No, however End date System is missing. Please provide.' (Site from System). | | 29 Jan 2021 20:29:45 |
| User opened query 'Ongoing is No, however End dateSystem is missing. Please provide.' (Site from System). | | 29 Jan 2021 20:29:33 |
| User entered empty. | Jessie Downs (b) (4) | 29 Jan 2021 20:29:33 |
| | (b) (4) | |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:33:17

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:05:21 |
| | | |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| | | |
| User entered 'No (N)' | Jessie Downs (b) (4) | 29 Jan 2021 20:29:33 |
| | (b) (4) | |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:33:17

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:05:21 |
| | | |
| User entered empty. | System | 29 Jan 2021 20:29:33 |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:33:17

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:05:21 |
| | | |
| User entered empty. | System | 29 Jan 2021 20:29:33 |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:33:17

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:05:21 |
| | | |
| User entered empty. | System | 29 Jan 2021 20:29:33 |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:33:17

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 29 Jan 2021 21:42:23 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 29 Jan 2021 21:42:23 |
| | (b) (4) | |
| Data point term sent to Coder | System | 29 Jan 2021 20:32:34 |
| User entered 'ibuprofen' | Jessie Downs (b) (4) | 29 Jan 2021 20:31:47 |
| | (b) (4) | |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:33:17

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'No (N)' | Jessie Downs (b) (4) (b) (4) | 29 Jan 2021 20:31:47 |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:33:17

[Indication](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'right rib cage pain - fractures' | Jessie Downs (b) (4) (b) (4) | 29 Jan 2021 20:31:47 |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:33:17

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered '600' | Jessie Downs (b) (4) (b) (4) | 29 Jan 2021 20:31:47 |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:33:17

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'mg (mg)' | Jessie Downs (b) (4) (b) (4) | 29 Jan 2021 20:31:47 |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:33:17

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered empty. | Jessie Downs (b) (4) (b) (4) | 29 Jan 2021 20:31:47 |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:33:17

[Frequency](#)

| Audit | User | Time (GMT) |
|------------------------------|---------------------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'other (OTHER)' | Jessie Downs (b) (4) (b) (4) | 29 Jan 2021 20:31:47 |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:33:17

If frequency is Other, specify

| Audit | User | Time (GMT) |
|------------------------------|---------------------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'every 6 hours' | Jessie Downs (b) (4) (b) (4) | 29 Jan 2021 20:31:47 |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:33:17

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'Oral (ORAL)' | Jessie Downs (b) (4) (b) (4) | 29 Jan 2021 20:31:47 |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:33:17

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered empty. | Jessie Downs (b) (4) (b) (4) | 29 Jan 2021 20:31:47 |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:33:17

Start date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered '23 Jan 2021' | Jessie Downs (b) (4) (b) (4) | 29 Jan 2021 20:31:47 |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:33:17

Start date completely unknown

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered '0' | Jessie Downs (b) (4) (b) (4) | 29 Jan 2021 20:31:47 |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:33:17

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'Yes (Y)' | Jessie Downs (b) (4) (b) (4) | 29 Jan 2021 20:31:47 |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:33:17

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered empty. | Jessie Downs (b) (4) (b) (4) | 29 Jan 2021 20:31:47 |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:33:17

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'No (N)' | Jessie Downs (b) (4) (b) (4) | 29 Jan 2021 20:31:47 |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:33:17

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 29 Jan 2021 20:31:47 |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:33:17

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 29 Jan 2021 20:31:47 |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:33:17

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 29 Jan 2021 20:31:47 |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:33:17

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 29 Jan 2021 20:34:23 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 29 Jan 2021 20:34:23 |
| | (b) (4) | |
| Data point term sent to Coder | System | 29 Jan 2021 20:33:34 |
| User entered 'tylenol' | Jessie Downs (b) (4) | 29 Jan 2021 20:32:43 |
| | (b) (4) | |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:33:17

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'No (N)' | Jessie Downs (b) (4) (b) (4) | 29 Jan 2021 20:32:43 |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:33:17

[Indication](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| User entered 'right rib cage pain - fractures' | Jessie Downs (b) (4) | 29 Jan 2021 20:32:43 |
| | (b) (4) | |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:33:17

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered '500' | Jessie Downs (b) (4) (b) (4) | 29 Jan 2021 20:32:43 |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:33:17

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'mg (mg)' | Jessie Downs (b) (4) (b) (4) | 29 Jan 2021 20:32:43 |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:33:17

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered empty. | Jessie Downs (b) (4) (b) (4) | 29 Jan 2021 20:32:43 |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:33:17

[Frequency](#)

| Audit | User | Time (GMT) |
|------------------------------|---------------------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'other (OTHER)' | Jessie Downs (b) (4) (b) (4) | 29 Jan 2021 20:32:43 |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:33:17

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|------------------------------|---------------------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'every 6 hours' | Jessie Downs (b) (4) (b) (4) | 29 Jan 2021 20:32:43 |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:33:17

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'Oral (ORAL)' | Jessie Downs (b) (4) (b) (4) | 29 Jan 2021 20:32:43 |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:33:17

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered empty. | Jessie Downs (b) (4) (b) (4) | 29 Jan 2021 20:32:43 |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:33:17

Start date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| User entered '23 Jan 2021' | Jessie Downs (b) (4) | 29 Jan 2021 20:32:43 |
| | (b) (4) | |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:33:17

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered '0' | Jessie Downs (b) (4) (b) (4) | 29 Jan 2021 20:32:43 |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:33:17

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'Yes (Y)' | Jessie Downs (b) (4) (b) (4) | 29 Jan 2021 20:32:43 |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:33:17

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered empty. | Jessie Downs (b) (4) (b) (4) | 29 Jan 2021 20:32:43 |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:33:17

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'No (N)' | Jessie Downs (b) (4) (b) (4) | 29 Jan 2021 20:32:43 |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:33:17

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 29 Jan 2021 20:32:43 |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:33:17

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 29 Jan 2021 20:32:43 |

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:33:17

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 29 Jan 2021 20:32:43 |

US3172224

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:33:17

[Were any concomitant procedures performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'No (N)' | Mariete Rendon (b) (4) (b) (4) | 02 Sep 2020 21:06:09 |

US3172224

Folder: SAE USA-US118-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:17

[SAEID](#)

| Audit | User | Time (GMT) |
|---|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:23:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| Reviewed for Safety. | (b) (4), (b) (6) | 01 Feb 2021 13:13:30 |
| User entered 'USA-US118-2021-MRNA-1273-P301000004' | System | 01 Feb 2021 13:12:30 |

US3172224

Folder: SAE USA-US118-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:17

Serious

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:23:53 |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 01 Feb 2021 13:13:30 |
| User entered 'Yes (Y)' | System | 01 Feb 2021 13:12:30 |

US3172224

Folder: SAE USA-US118-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:17

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:23:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| Reviewed for Safety. | (b) (4), (b) (6) | 01 Feb 2021 13:13:30 |
| User entered 'No (N)' | System | 01 Feb 2021 13:12:30 |

US3172224

Folder: SAE USA-US118-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:17

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:23:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| Reviewed for Safety. | (b) (4), (b) (6) | 01 Feb 2021 13:13:30 |
| User entered 'No (N)' | System | 01 Feb 2021 13:12:30 |

US3172224

Folder: SAE USA-US118-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:17

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:23:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| Reviewed for Safety. | (b) (4), (b) (6) | 01 Feb 2021 13:13:30 |
| User entered 'Yes (Y)' | System | 01 Feb 2021 13:12:30 |

US3172224

Folder: SAE USA-US118-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:17

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:23:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| Reviewed for Safety. | (b) (4), (b) (6) | 01 Feb 2021 13:13:30 |
| User entered 'No (N)' | System | 01 Feb 2021 13:12:30 |

US3172224

Folder: SAE USA-US118-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:17

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:23:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| Reviewed for Safety. | (b) (4), (b) (6) | 01 Feb 2021 13:13:30 |
| User entered 'No (N)' | System | 01 Feb 2021 13:12:30 |

US3172224

Folder: SAE USA-US118-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:17

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:23:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| Reviewed for Safety. | (b) (4), (b) (6) | 01 Feb 2021 13:13:30 |
| User entered 'No (N)' | System | 01 Feb 2021 13:12:30 |

US3172224

Folder: SAE USA-US118-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:17

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:23:53 |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 01 Feb 2021 13:13:30 |
| User entered 'Mark' | System | 01 Feb 2021 13:12:30 |

US3172224

Folder: SAE USA-US118-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:17

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:23:53 |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 01 Feb 2021 13:13:30 |
| User entered 'Kutner' | System | 01 Feb 2021 13:12:30 |

US3172224

Folder: SAE USA-US118-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:17

[Site Address: State](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:23:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| Reviewed for Safety. | (b) (4), (b) (6) | 01 Feb 2021 13:13:30 |
| User entered 'FL' | System | 01 Feb 2021 13:12:30 |

US3172224

Folder: SAE USA-US118-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:17

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:23:53 |
| Reviewed for Safety. | (b) (4), (b) (6) | 08 Apr 2021 14:28:54 |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| User entered 'US' | System | 01 Feb 2021 13:13:49 |

US3172224

Folder: SAE USA-US118-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:17

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| User entered '2' | System | 08 Apr 2021 14:29:11 |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| | | |
| User entered '1' | System | 01 Feb 2021 13:13:49 |

US3172224

Folder: SAE USA-US118-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:17

[SAEID](#)

| Audit | User | Time (GMT) |
|---|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:23:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| Reviewed for Safety. | (b) (4), (b) (6) | 01 Feb 2021 13:13:30 |
| User entered 'USA-US118-2021-MRNA-1273-P301000004' | System | 01 Feb 2021 13:12:30 |

US3172224

Folder: SAE USA-US118-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:17

[Serious](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:23:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| Reviewed for Safety. | (b) (4), (b) (6) | 01 Feb 2021 13:13:30 |
| User entered 'Yes (Y)' | System | 01 Feb 2021 13:12:30 |

US3172224

Folder: SAE USA-US118-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:17

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:23:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| Reviewed for Safety. | (b) (4), (b) (6) | 01 Feb 2021 13:13:30 |
| User entered 'No (N)' | System | 01 Feb 2021 13:12:30 |

US3172224

Folder: SAE USA-US118-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:17

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:23:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| Reviewed for Safety. | (b) (4), (b) (6) | 01 Feb 2021 13:13:30 |
| User entered 'No (N)' | System | 01 Feb 2021 13:12:30 |

US3172224

Folder: SAE USA-US118-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:17

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:23:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| Reviewed for Safety. | (b) (4), (b) (6) | 01 Feb 2021 13:13:30 |
| User entered 'Yes (Y)' | System | 01 Feb 2021 13:12:30 |

US3172224

Folder: SAE USA-US118-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:17

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:23:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| Reviewed for Safety. | (b) (4), (b) (6) | 01 Feb 2021 13:13:30 |
| User entered 'No (N)' | System | 01 Feb 2021 13:12:30 |

US3172224

Folder: SAE USA-US118-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:17

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:23:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| Reviewed for Safety. | (b) (4), (b) (6) | 01 Feb 2021 13:13:30 |
| User entered 'No (N)' | System | 01 Feb 2021 13:12:30 |

US3172224

Folder: SAE USA-US118-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:17

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:23:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| Reviewed for Safety. | (b) (4), (b) (6) | 01 Feb 2021 13:13:30 |
| User entered 'No (N)' | System | 01 Feb 2021 13:12:30 |

US3172224

Folder: SAE USA-US118-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:17

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:23:53 |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 01 Feb 2021 13:13:30 |
| User entered 'Mark' | System | 01 Feb 2021 13:12:30 |

US3172224

Folder: SAE USA-US118-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:17

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:23:53 |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 01 Feb 2021 13:13:30 |
| User entered 'Kutner' | System | 01 Feb 2021 13:12:30 |

US3172224

Folder: SAE USA-US118-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:17

[Site Address: State](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:23:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| Reviewed for Safety. | (b) (4), (b) (6) | 01 Feb 2021 13:13:30 |
| User entered 'FL' | System | 01 Feb 2021 13:12:30 |

US3172224

Folder: SAE USA-US118-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:17

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:23:53 |
| Reviewed for Safety. | (b) (4), (b) (6) | 08 Apr 2021 14:28:54 |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| User entered 'US' | System | 01 Feb 2021 13:13:49 |

US3172224

Folder: SAE USA-US118-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:17

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| User entered '2' | System | 08 Apr 2021 14:29:11 |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| | | |
| User entered '1' | System | 01 Feb 2021 13:13:49 |

US3172224

Folder: SAE USA-US118-2021-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:33:17

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|---------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:23:53 |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| User entered '01/Feb/2021 13:13' | System | 01 Feb 2021 13:13:49 |

US3172224

Folder: SAE USA-US118-2021-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:33:17

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) | 19 Apr 2021 16:23:53 |
| Reviewed for Safety. | (b) (4), (b) (6) | 08 Apr 2021 14:28:54 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| User entered 'I' | (b) (4), (b) (6) | 01 Feb 2021 13:13:49 |

US3172224

Folder: SAE USA-US118-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:17

[SAEID](#)

| Audit | User | Time (GMT) |
|---|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:23:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| Reviewed for Safety. | (b) (4), (b) (6) | 01 Feb 2021 13:13:30 |
| User entered 'USA-US118-2021-MRNA-1273-P301000004' | System | 01 Feb 2021 13:12:30 |

US3172224

Folder: SAE USA-US118-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:17

Serious

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:23:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| Reviewed for Safety. | (b) (4), (b) (6) | 01 Feb 2021 13:13:30 |
| User entered 'Yes (Y)' | System | 01 Feb 2021 13:12:30 |

US3172224

Folder: SAE USA-US118-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:17

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:23:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| Reviewed for Safety. | (b) (4), (b) (6) | 01 Feb 2021 13:13:30 |
| User entered 'No (N)' | System | 01 Feb 2021 13:12:30 |

US3172224

Folder: SAE USA-US118-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:17

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:23:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| Reviewed for Safety. | (b) (4), (b) (6) | 01 Feb 2021 13:13:30 |
| User entered 'No (N)' | System | 01 Feb 2021 13:12:30 |

US3172224

Folder: SAE USA-US118-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:17

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:23:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| Reviewed for Safety. | (b) (4), (b) (6) | 01 Feb 2021 13:13:30 |
| User entered 'Yes (Y)' | System | 01 Feb 2021 13:12:30 |

US3172224

Folder: SAE USA-US118-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:17

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:23:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| Reviewed for Safety. | (b) (4), (b) (6) | 01 Feb 2021 13:13:30 |
| User entered 'No (N)' | System | 01 Feb 2021 13:12:30 |

US3172224

Folder: SAE USA-US118-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:17

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:23:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| Reviewed for Safety. | (b) (4), (b) (6) | 01 Feb 2021 13:13:30 |
| User entered 'No (N)' | System | 01 Feb 2021 13:12:30 |

US3172224

Folder: SAE USA-US118-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:17

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:23:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| Reviewed for Safety. | (b) (4), (b) (6) | 01 Feb 2021 13:13:30 |
| User entered 'No (N)' | System | 01 Feb 2021 13:12:30 |

US3172224

Folder: SAE USA-US118-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:17

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:23:53 |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 01 Feb 2021 13:13:30 |
| User entered 'Mark' | System | 01 Feb 2021 13:12:30 |

US3172224

Folder: SAE USA-US118-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:17

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:23:53 |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 01 Feb 2021 13:13:30 |
| User entered 'Kutner' | System | 01 Feb 2021 13:12:30 |

US3172224

Folder: SAE USA-US118-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:17

[Site Address: State](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:23:53 |
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 17 Feb 2021 13:11:39 |
| Reviewed for Safety. | (b) (4), (b) (6) | 01 Feb 2021 13:13:30 |
| User entered 'FL' | System | 01 Feb 2021 13:12:30 |

US3172224

Folder: SAE USA-US118-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:17

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:23:53 |
| Reviewed for Safety. | (b) (4), (b) (6) | 08 Apr 2021 14:28:54 |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| User entered 'US' | System | 01 Feb 2021 13:13:49 |

US3172224

Folder: SAE USA-US118-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:17

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| User entered '2' | System | 08 Apr 2021 14:29:11 |
| User signature succeeded. | Mark Kutner (b) (4) | 17 Feb 2021 13:11:39 |
| | (b) (4) | |
| | | |
| User entered '1' | System | 01 Feb 2021 13:13:49 |

US3172224

Folder: SAE USA-US118-2021-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:33:17

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------------------------------|----------------------|
| User signature succeeded. | Mark Kutner (b) (4) (b) (4) | 22 Apr 2021 16:25:33 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:23:53 |
| User entered '08/Apr/2021 10:29' | System | 08 Apr 2021 14:29:11 |

US3172224

Folder: SAE USA-US118-2021-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:33:17

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. | Mark Kutner (b) (4) (b) (4) | 22 Apr 2021 16:25:33 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Apr 2021 16:23:53 |
| User entered 'I' | (b) (4), (b) (6) | 08 Apr 2021 14:29:11 |