

US3362244 (Prod: Meridian Clinical Research-(Baton Rouge, Louisiana) - Platinum - PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:14:58

All time stamps listed in this document are displayed in GMT

US3362244

Form: Participant Creation

Data signed: (b) (4) 25 Apr 2021 01:32:36

Generated On: 09 Jun 2021 17:14:58

[Participant ID](#)

US3362244

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

US3362244

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 10 Apr 2021 00:36:58

Generated On: 09 Jun 2021 17:14:58

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 24 AUG 2020 |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/> |
| | Clinic <input checked="" type="radio"/> |
| Folder OID | SCRN |

US3362244

Folder: Screening

Form: Demographics

Data signed: (b) (4) 10 Apr 2021 00:36:58

Generated On: 09 Jun 2021 17:14:58

| | |
|---|--|
| Date of Birth (MMM yyyy) | (b) (6) 1954 |
| Age | 66 |
| Age Units | YEARS |
| Age (Derived) | 66 |
| Sex | Female <input checked="" type="radio"/> Male <input type="radio"/> |
| Ethnicity | Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/> |
| Race (Check All That Apply) | |
| White | True |
| Black | False |
| Asian | False |
| American Indian or Alaska Native | False |
| Native Hawaiian or other Pacific Islander | False |
| Other | False |
| If race is Other, specify _____ | |
| Unknown | False |
| Not reported | False |

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 10 Apr 2021 00:36:58

Generated On: 09 Jun 2021 17:14:58

| | |
|---|--|
| Date of Informed Consent (<i>dd MMM yyyy</i>) | 24 AUG 2020 |
| Month and Year of Informed Consent (derived) | AUG 2020 |
| Year of Informed Consent (derived) | 2020 |
| Protocol Version | Amendment 1 <input type="radio"/> |
| | Amendment 2 <input checked="" type="radio"/> |
| | Amendment 3 <input type="radio"/> |
| | Amendment 4 <input type="radio"/> |
| | Amendment 5 <input type="radio"/> |
| Was participant enrolled in the study? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| If No, indicate reason for screen fail | Withdrew Consent <input type="radio"/> |
| | Inclusion/Exclusion <input type="radio"/> |
| | Cohort Full <input type="radio"/> |
| | Other <input type="radio"/> |
| If reason for screen fail is Other, specify | |
| Was this participant screened previously? | Yes <input type="radio"/> |
| | No <input checked="" type="radio"/> |
| If Yes, previous participant number | |
| Enrollment Trigger | 1 |

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 10 Apr 2021 00:36:58

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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) 10 Apr 2021 00:36:58

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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) 10 Apr 2021 00:36:58

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| | |
|---|--|
| Condition | OSTEOPOROSIS |
| 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 (2)

Data signed: (b) (4) 10 Apr 2021 00:36:58

Generated On: 09 Jun 2021 17:14:58

| | |
|---|--|
| Condition | HYPERLIPIDEMIA |
| Start date (dd MMM yyyy) | UN UNK 2015 |
| 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 2015 |
| Start Year (derived) | 2015 |
| Stop Month and Year (derived) | _____ |
| Stop Year (derived) | _____ |

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 10 Apr 2021 00:36:58

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| | |
|---|--|
| Condition | FRACTURED PELVIS (LEFT PELVIC RING NON-UNION) |
| Start date (dd MMM yyyy) | UN FEB 2020 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) | |
| Stop date completely unknown | False |
| Start Month and Year (derived) | FEB 2020 |
| Start Year (derived) | 2020 |
| Stop Month and Year (derived) | |
| Stop Year (derived) | |

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 10 Apr 2021 00:36:58

Generated On: 09 Jun 2021 17:14:58

| | |
|---|--|
| Condition | OSTEOARTHRITIS BILATERAL HANDS |
| 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 (5)

Data signed: (b) (4) 10 Apr 2021 00:36:58

Generated On: 09 Jun 2021 17:14:58

| | |
|---|--|
| Condition | POST MENOPAUSE |
| Start date (dd MMM yyyy) | |
| Start date completely unknown | True |
| 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) | |
| Start Year (derived) | |
| Stop Month and Year (derived) | |
| Stop Year (derived) | |

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 10 Apr 2021 00:36:58

Generated On: 09 Jun 2021 17:14:58

| | |
|---|--|
| Condition | ALPHA THALASSEMIA |
| Start date (dd MMM yyyy) | |
| Start date completely unknown | True |
| 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) | |
| Start Year (derived) | |
| Stop Month and Year (derived) | |
| Stop Year (derived) | |

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 10 Apr 2021 00:36:58

Generated On: 09 Jun 2021 17:14:58

| | |
|---|--|
| Condition | FRACTURED LEFT ELBOW |
| Start date (dd MMM yyyy) | UN FEB 2020 |
| 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 FEB 2020 |
| Stop date completely unknown | False |
| Start Month and Year (derived) | FEB 2020 |
| Start Year (derived) | 2020 |
| Stop Month and Year (derived) | FEB 2020 |
| Stop Year (derived) | 2020 |

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 10 Apr 2021 00:36:58

Generated On: 09 Jun 2021 17:14:58

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

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 10 Apr 2021 00:36:58

Generated On: 09 Jun 2021 17:14:58

| | |
|---|--|
| Condition | DEGENERATIVE DISC DISEASE |
| Start date (dd MMM yyyy) | 27 APR 2020 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) | |
| Stop date completely unknown | False |
| Start Month and Year (derived) | APR 2020 |
| Start Year (derived) | 2020 |
| Stop Month and Year (derived) | |
| Stop Year (derived) | |

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 10 Apr 2021 00:36:58

Generated On: 09 Jun 2021 17:14:58

| | |
|---|--|
| Condition | ABNORMAL HEART RHYTHM |
| Start date (dd MMM yyyy) | |
| Start date completely unknown | True |
| 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) | |
| Start Year (derived) | |
| Stop Month and Year (derived) | |
| Stop Year (derived) | |

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 10 Apr 2021 00:36:58

Generated On: 09 Jun 2021 17:14:58

| | |
|---|--------------------------------------|
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (<i>dd MMM yyyy</i>) | 24 AUG 2020 |
| Time of assessment (<i>00:00-23:59</i>) | 13:54 (24 HR) |
| Vital Signs Date and Time (derived) | 24 AUG 2020 13:54 |
| Height (<i>xxx.x</i>) | 164.2 cm |
| Weight (<i>xxx.x</i>) | 55.7 kg |
| BMI (<i>xxx.x</i>) | 20.65898 kg/m ² |
| BMI units | KG/M2 |
| Temperature (<i>xxx.x</i>) | ND - Not Done |
| Route of measurement | Oral <input type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (<i>xxx</i>) | ND - Not Done |
| Pulse units | BPM |
| Respiratory Rate (<i>xxx</i>) | ND - Not Done |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (<i>xxx</i>) | ND - Not Done |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (<i>xxx</i>) | ND - Not Done |
| Diastolic Blood Pressure units | MMHG |
| Height (derived) | |
| Weight (derived) | |

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 10 Apr 2021 00:36:58

Generated On: 09 Jun 2021 17:14:58

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

24 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 10 Apr 2021 00:36:58

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Date of assessment (dd MMM yyyy) 24 AUG 2020

Is the participant of childbearing potential? Yes ☐
No ☒

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

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 10 Apr 2021 00:36:58

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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) 10 Apr 2021 00:36:58

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| | |
|--|---|
| Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs) | False |
| Resides in high density housing (e.g., high rise apartments with shared entrances or elevators) | False |
| Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes) | False |
| Resides in a single family home (i.e., detached housing) | False |
| Other | True |
| Specify | LIVES IN A BED AND BREAKFAST (b) (6) |

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 18:06:31

Generated On: 09 Jun 2021 17:14:58

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 24 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) 20 Feb 2021 18:06:31

Generated On: 09 Jun 2021 17:14:58

What was the date of randomization? (dd MMM yyyy) 24 AUG 2020

What was the participant's randomization number? 187957

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 20 Feb 2021 18:06:31

Generated On: 09 Jun 2021 17:14:58

| | |
|--------|---------------|
| 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) 20 Feb 2021 18:06:31

Generated On: 09 Jun 2021 17:14:58

| | |
|-------------------------------------|--|
| 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) | 24 AUG 2020 |
| Time of assessment (00:00-23:59) | 13:54 (24 HR) |
| Vital Signs Date and Time (derived) | 24 AUG 2020 13:54 |
| 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) | 70 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 18 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 158 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 95 mmHg |
| Diastolic Blood Pressure units | MMHG |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 20 Feb 2021 18:06:31

Generated On: 09 Jun 2021 17:14:58

| | |
|-------------------------------------|--|
| 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) | 24 AUG 2020 |
| Time of assessment (00:00-23:59) | 15:37 (24 HR) |
| Vital Signs Date and Time (derived) | 24 AUG 2020 15:37 |
| Temperature (xxx.x) | 36.8 C |
| Route of measurement | Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 62 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 18 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 130 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 81 mmHg |
| Diastolic Blood Pressure units | MMHG |

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 18:06:31

Generated On: 09 Jun 2021 17:14:58

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

24 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) 20 Feb 2021 18:06:31

Generated On: 09 Jun 2021 17:14:58

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) 24 AUG 2020

What was the treatment time? (00:00-23:59) 14:58 (24 HR)

Treatment Date and Time (derived) 24 AUG 2020 14:58

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) 20 Feb 2021 18:06:31

Generated On: 09 Jun 2021 17:14:58

| | |
|------------------------------------|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (dd MMM yyyy) | 24 AUG 2020 |
| Collection time (00:00-23:59) | 14:32 (24 HR) |
| Collection date and time (derived) | 24 AUG 2020 14:32 |

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 20 Feb 2021 18:06:31

Generated On: 09 Jun 2021 17:14:58

| | | | |
|-------------------------------|---------------------------|---------------------------------|------------------------------------|
| Collection date (dd MMM yyyy) | | | 24 AUG 2020 |
| Lab Test | Was the sample collected? | Collection time (00:00 - 23:59) | Collection date and time (derived) |
| Nasopharyngeal Swab 1 | Yes | 14:12 | 24 AUG 2020 14:12 |
| Nasopharyngeal Swab 2 | No | | |

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 18:06:31

Generated On: 09 Jun 2021 17:14:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:14:58

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

24 AUG 2020 15:32

PC Open Date & Time

24 AUG 2020 15:18

PC Close Date & Time

24 AUG 2020 17:48

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:14:58

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

97.3 °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

24 AUG 2020 20:25

PC Open Date & Time

24 AUG 2020 18:43

PC Close Date & Time

25 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:14:58

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 | 97.3 °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 | False |
| To PREVENT pain or fever from occurring | True |

| | |
|----------------------|-------------------|
| PC Time Stamp | 25 AUG 2020 12:37 |
| PC Open Date & Time | 25 AUG 2020 12:00 |
| PC Close Date & Time | 26 AUG 2020 11:59 |

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:14:58

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 <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Please record your TEMPERATURE in °F | 96.7 °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 | False |
| To PREVENT pain or fever from occurring | True |

| | |
|----------------------|-------------------|
| PC Time Stamp | 26 AUG 2020 13:17 |
| PC Open Date & Time | 26 AUG 2020 12:00 |
| PC Close Date & Time | 27 AUG 2020 11:59 |

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °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):

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

False

To **PREVENT** pain or fever from occurring

True

PC Time Stamp

27 AUG 2020 12:27

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:14:58

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

96.4 °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

28 AUG 2020 12:09

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °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

29 AUG 2020 12:17

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:14:58

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

96.8 °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

30 AUG 2020 12:23

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

24 AUG 2020 15:33

PC Open Date & Time

24 AUG 2020 15:18

PC Close Date & Time

24 AUG 2020 17:48

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:14:58

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

24 AUG 2020 20:26

PC Open Date & Time

24 AUG 2020 18:43

PC Close Date & Time

25 AUG 2020 11:59

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:14:58

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

25 AUG 2020 12:38

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:14:58

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

26 AUG 2020 13:18

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:14:58

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

27 AUG 2020 12:28

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:14:58

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

28 AUG 2020 12:10

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:14:58

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

29 AUG 2020 12:17

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:14:58

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

30 AUG 2020 12:24

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:14:58

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 ☐

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:14:58

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 24 AUG 2020 15:35 |
| PC Open Date & Time | 24 AUG 2020 15:18 |
| PC Close Date & Time | 24 AUG 2020 17:48 |

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:14:58

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 ☐

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:14:58

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 24 AUG 2020 20:29 |
| PC Open Date & Time | 24 AUG 2020 18:43 |
| PC Close Date & Time | 25 AUG 2020 11:59 |

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:14:58

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 25 AUG 2020 12:39 |
| PC Open Date & Time | 25 AUG 2020 12:00 |
| PC Close Date & Time | 26 AUG 2020 11:59 |

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:14:58

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 26 AUG 2020 13:19 |
| PC Open Date & Time | 26 AUG 2020 12:00 |
| PC Close Date & Time | 27 AUG 2020 11:59 |

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:14:58

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

56 of 2497

EAB) (1725)

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:14:58

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 27 AUG 2020 12:29 |
| PC Open Date & Time | 27 AUG 2020 12:00 |
| PC Close Date & Time | 28 AUG 2020 11:59 |

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:14:58

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

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EAB) (1725)

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:14:58

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 28 AUG 2020 12:10 |
| PC Open Date & Time | 28 AUG 2020 12:00 |
| PC Close Date & Time | 29 AUG 2020 11:59 |

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:14:58

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

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EAB) (1725)

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:14:58

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 29 AUG 2020 12:18 |
| PC Open Date & Time | 29 AUG 2020 12:00 |
| PC Close Date & Time | 30 AUG 2020 11:59 |

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:14:58

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

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EAB) (1725)

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:14:58

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 30 AUG 2020 12:24 |
| PC Open Date & Time | 30 AUG 2020 12:00 |
| PC Close Date & Time | 31 AUG 2020 11:59 |

US3362244

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 18:06:31

Generated On: 09 Jun 2021 17:14:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

31 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3362244

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 18:06:31

Generated On: 09 Jun 2021 17:14:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362244

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 18:06:31

Generated On: 09 Jun 2021 17:14:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

08 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3362244

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 18:06:31

Generated On: 09 Jun 2021 17:14:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362244

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 18:06:31

Generated On: 09 Jun 2021 17:14:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3362244

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 18:06:31

Generated On: 09 Jun 2021 17:14:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362244

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 18:06:31

Generated On: 09 Jun 2021 17:14:58

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 23 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 |

US3362244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 20 Feb 2021 18:06:31

Generated On: 09 Jun 2021 17:14:58

| | |
|-------------------------------------|---|
| 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) | 23 SEP 2020 |
| Time of assessment (00:00-23:59) | 14:20 (24 HR) |
| Vital Signs Date and Time (derived) | 23 SEP 2020 14:20 |
| Temperature (xxx.x) | 37.5 C |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 90 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 16 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 110 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 75 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3362244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 20 Feb 2021 18:06:31

Generated On: 09 Jun 2021 17:14:58

| | |
|-------------------------------------|---|
| Timepoint | Pre-Dose <input type="checkbox"/> |
| | Post-Dose <input checked="" type="checkbox"/> |
| Were vital signs assessed? | Yes <input type="checkbox"/> |
| | No <input checked="" type="checkbox"/> |
| 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 <input type="checkbox"/> |
| | Axillary <input type="checkbox"/> |
| | Other <input type="checkbox"/> |
| 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 | |

US3362244

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 18:06:31

Generated On: 09 Jun 2021 17:14:58

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 SEP 2020

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

US3362244

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 20 Feb 2021 18:06:31

Generated On: 09 Jun 2021 17:14:58

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

PATIENT DECLINED SECOND DOSE DUE TO ORTHOPEDIC SURGERY BEING NEEDED

What was the study treatment? _____

What was the treatment date? (dd MMM yyyy) _____

What was the treatment time? (00:00-23:59) _____

Treatment Date and Time (derived) _____

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

What was the frequency of the study treatment dosing? _____

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

US3362244

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 20 Feb 2021 18:06:31

Generated On: 09 Jun 2021 17:14:58

| | |
|------------------------------------|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (dd MMM yyyy) | 23 SEP 2020 |
| Collection time (00:00-23:59) | 14:35 (24 HR) |
| Collection date and time (derived) | 23 SEP 2020 14:35 |

US3362244

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 20 Feb 2021 18:06:31

Generated On: 09 Jun 2021 17:14:58

| | | | |
|-------------------------------|---------------------------|---------------------------------|------------------------------------|
| Collection date (dd MMM yyyy) | | | 23 SEP 2020 |
| Lab Test | Was the sample collected? | Collection time (00:00 - 23:59) | Collection date and time (derived) |
| Nasopharyngeal Swab 1 | Yes | 14:42 | 23 SEP 2020 14:42 |
| Nasopharyngeal Swab 2 | No | | |

US3362244

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 18:06:31

Generated On: 09 Jun 2021 17:14:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362244

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 18:06:31

Generated On: 09 Jun 2021 17:14:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

02 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3362244

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 18:06:31

Generated On: 09 Jun 2021 17:14:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362244

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 18:06:31

Generated On: 09 Jun 2021 17:14:58

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

US3362244

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 18:06:31

Generated On: 09 Jun 2021 17:14:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362244

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 18:06:31

Generated On: 09 Jun 2021 17:14:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3362244

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 18:06:31

Generated On: 09 Jun 2021 17:14:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362244

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 18:06:31

Generated On: 09 Jun 2021 17:14:58

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 28 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 |

US3362244

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 20 Feb 2021 18:06:31

Generated On: 09 Jun 2021 17:14:58

| | |
|-------------------------------------|---------------------------------------|
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 28 OCT 2020 |
| Time of assessment (00:00-23:59) | 12:38 (24 HR) |
| Vital Signs Date and Time (derived) | 28 OCT 2020 12:38 |
| 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) | 90 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 18 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 127 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 90 mmHg |
| Diastolic Blood Pressure units | MMHG |
| Height (derived) | |
| Weight (derived) | |

US3362244

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 18:06:31

Generated On: 09 Jun 2021 17:14:58

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 OCT 2020

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

US3362244

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 20 Feb 2021 18:06:31

Generated On: 09 Jun 2021 17:14:58

| | |
|------------------------------------|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (dd MMM yyyy) | 28 OCT 2020 |
| Collection time (00:00-23:59) | 12:50 (24 HR) |
| Collection date and time (derived) | 28 OCT 2020 12:50 |

US3362244

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 18:06:31

Generated On: 09 Jun 2021 17:14:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

| TIMEPOINT | DAY 64 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input 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 | 26 OCT 2020 13:03:21 |
| Patient Cloud Open Date & Time | 24 OCT 2020 00:01 |
| Patient Cloud Close Date & Time | 28 OCT 2020 23:59 |

US3362244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

31 OCT 2020 09:19:18

Patient Cloud Open Date & Time

31 OCT 2020 00:01

Patient Cloud Close Date & Time

04 NOV 2020 23:59

US3362244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

| TIMEPOINT | DAY 78 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> 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"/> |

US3362244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

07 NOV 2020 00:01

Patient Cloud Close Date & Time

11 NOV 2020 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

| TIMEPOINT | DAY 89 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <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"/> |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2020 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

| TIMEPOINT | DAY 96 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input 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"/> |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

[Patient Cloud Close Date & Time](#)

29 NOV 2020 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

DAY 103

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your 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 DEC 2020 00:01 |
| Patient Cloud Close Date & Time | 06 DEC 2020 23:59 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your 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 DEC 2020 00:01 |
| Patient Cloud Close Date & Time | 13 DEC 2020 23:59 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

| 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 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"/> |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

[Patient Cloud Close Date & Time](#)

20 DEC 2020 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

| TIMEPOINT | DAY 124 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="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"/> |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

| | |
|---|-------------------|
| Patient Cloud Close Date & Time | 27 DEC 2020 23:59 |
|---|-------------------|

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

[Patient Cloud Close Date & Time](#)

03 JAN 2021 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

DAY 138

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

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

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

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

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

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

[Patient Cloud Close Date & Time](#)

10 JAN 2021 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

| | |
|---|--|
| 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 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 | 14 JAN 2021 08:55:20 |
| Patient Cloud Open Date & Time | 13 JAN 2021 00:01 |
| Patient Cloud Close Date & Time | 17 JAN 2021 23:59 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

20 JAN 2021 09:11:28

Patient Cloud Open Date & Time

20 JAN 2021 00:01

Patient Cloud Close Date & Time

24 JAN 2021 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

| 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 checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 27 JAN 2021 18:15:08 |
| Patient Cloud Open Date & Time | 27 JAN 2021 00:01 |
| Patient Cloud Close Date & Time | 31 JAN 2021 23:59 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 FEB 2021 08:53:29

Patient Cloud Open Date & Time

03 FEB 2021 00:01

Patient Cloud Close Date & Time

07 FEB 2021 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

10 FEB 2021 11:50:53

Patient Cloud Open Date & Time

10 FEB 2021 00:01

Patient Cloud Close Date & Time

14 FEB 2021 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 FEB 2021 16:35:20

Patient Cloud Open Date & Time

17 FEB 2021 00:01

Patient Cloud Close Date & Time

21 FEB 2021 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

| TIMEPOINT | DAY 187 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input 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 | 24 FEB 2021 01:09:48 |
| Patient Cloud Open Date & Time | 24 FEB 2021 00:01 |
| Patient Cloud Close Date & Time | 28 FEB 2021 23:59 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

[Patient Cloud Close Date & Time](#)

07 MAR 2021 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

| TIMEPOINT | DAY 201 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input 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 | 10 MAR 2021 02:14:03 |
| Patient Cloud Open Date & Time | 10 MAR 2021 00:01 |
| Patient Cloud Close Date & Time | 14 MAR 2021 23:59 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

17 MAR 2021 19:36:37

Patient Cloud Open Date & Time

17 MAR 2021 00:01

Patient Cloud Close Date & Time

21 MAR 2021 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

DAY 215

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

[Patient Cloud Close Date & Time](#)

28 MAR 2021 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

| 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 <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"/> |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

[Patient Cloud Close Date & Time](#)

04 APR 2021 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

| 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 <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"/> |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

[Patient Cloud Close Date & Time](#)

11 APR 2021 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

[Patient Cloud Close Date & Time](#)

18 APR 2021 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

| TIMEPOINT | DAY 243 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="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"/> |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

29 APR 2021 13:25:27

Patient Cloud Open Date & Time

28 APR 2021 00:01

Patient Cloud Close Date & Time

02 MAY 2021 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

DAY 257

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2021 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

DAY 264

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2021 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

| 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"/> |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2021 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

DAY 278

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2021 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

DAY 285

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

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

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

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

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

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

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

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2021 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

| TIMEPOINT | DAY 299 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> 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"/> |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

[Patient Cloud Close Date & Time](#)

20 JUN 2021 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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 ☐

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

| 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 <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"/> |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2021 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

| 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"/> |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2021 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

| 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 <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"/> |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 14 JUL 2021 00:01 |
| Patient Cloud Close Date & Time | 18 JUL 2021 23:59 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

| TIMEPOINT | DAY 334 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> 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"/> |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 21 JUL 2021 00:01 |
| Patient Cloud Close Date & Time | 25 JUL 2021 23:59 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

| 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"/> |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2021 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

| 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"/> |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2021 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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 ☐

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

[Patient Cloud Close Date & Time](#)

15 AUG 2021 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

| TIMEPOINT | DAY 362 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="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"/> |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

[Patient Cloud Close Date & Time](#)

22 AUG 2021 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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 ☐

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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°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 ☐

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2021 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

| 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 <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"/> |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

19 SEP 2021 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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 ☐

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2021 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

| TIMEPOINT | DAY 404 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

[Patient Cloud Close Date & Time](#)

03 OCT 2021 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

| TIMEPOINT | DAY 411 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> 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"/> |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 06 OCT 2021 00:01 |
| Patient Cloud Close Date & Time | 10 OCT 2021 23:59 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

| TIMEPOINT | DAY 418 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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 ☐

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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 ☐

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

31 OCT 2021 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

07 NOV 2021 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

| TIMEPOINT | DAY 446 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="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"/> |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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 ☐

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 17 NOV 2021 00:01 |
| Patient Cloud Close Date & Time | 21 NOV 2021 23:59 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

28 NOV 2021 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

| 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"/> |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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 ☐

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

| 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"/> |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 15 DEC 2021 00:01 |
| Patient Cloud Close Date & Time | 19 DEC 2021 23:59 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 22 DEC 2021 00:01 |
| Patient Cloud Close Date & Time | 26 DEC 2021 23:59 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

| 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"/> |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 29 DEC 2021 00:01 |
| Patient Cloud Close Date & Time | 02 JAN 2022 23:59 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

DAY 502

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

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

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

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

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

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

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

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JAN 2022 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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°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 ☐

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 12 JAN 2022 00:01 |
| Patient Cloud Close Date & Time | 16 JAN 2022 23:59 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JAN 2022 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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 ☐

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JAN 2022 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

| TIMEPOINT | DAY 530 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

06 FEB 2022 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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 ☐

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

13 FEB 2022 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

| TIMEPOINT | DAY 544 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

20 FEB 2022 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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 ☐

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 23 FEB 2022 00:01 |
| Patient Cloud Close Date & Time | 27 FEB 2022 23:59 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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 ☐

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

06 MAR 2022 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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 ☐

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 MAR 2022 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

20 MAR 2022 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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 ☐

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 MAR 2022 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

| 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 <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"/> |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 APR 2022 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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°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 ☐

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

10 APR 2022 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

| 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="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"/> |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 13 APR 2022 00:01 |
| Patient Cloud Close Date & Time | 17 APR 2022 23:59 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

| TIMEPOINT | DAY 607 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 20 APR 2022 00:01 |
| Patient Cloud Close Date & Time | 24 APR 2022 23:59 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

| TIMEPOINT | DAY 614 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAY 2022 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAY 2022 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAY 2022 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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 ☐

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAY 2022 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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 ☐

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAY 2022 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUN 2022 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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 ☐

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JUN 2022 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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 ☐

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 15 JUN 2022 00:01 |
| Patient Cloud Close Date & Time | 19 JUN 2022 23:59 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

| TIMEPOINT | DAY 670 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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 ☐

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 29 JUN 2022 00:01 |
| Patient Cloud Close Date & Time | 03 JUL 2022 23:59 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

| TIMEPOINT | DAY 684 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="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"/> |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JUL 2022 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

| 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"/> |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 13 JUL 2022 00:01 |
| Patient Cloud Close Date & Time | 17 JUL 2022 23:59 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

| TIMEPOINT | DAY 698 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="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"/> |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JUL 2022 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 27 JUL 2022 00:01 |
| Patient Cloud Close Date & Time | 31 JUL 2022 23:59 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

07 AUG 2022 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

| 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="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"/> |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

Date and time of submission

| | |
|--|-------------------|
| Patient Cloud Open Date & Time | 10 AUG 2022 00:01 |
|--|-------------------|

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|---|-------------------|
| Patient Cloud Close Date & Time | 14 AUG 2022 23:59 |
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US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

| TIMEPOINT | DAY 726 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> 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"/> |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 17 AUG 2022 00:01 |
| Patient Cloud Close Date & Time | 21 AUG 2022 23:59 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

| TIMEPOINT | DAY 733 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 24 AUG 2022 00:01 |
| Patient Cloud Close Date & Time | 28 AUG 2022 23:59 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

[Patient Cloud Close Date & Time](#)

04 SEP 2022 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

| TIMEPOINT | DAY 747 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

11 SEP 2022 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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 ☐

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

18 SEP 2022 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

| 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 <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"/> |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

25 SEP 2022 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

02 OCT 2022 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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 ☐

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 05 OCT 2022 00:01 |
| Patient Cloud Close Date & Time | 09 OCT 2022 23:59 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 12 OCT 2022 00:01 |
| Patient Cloud Close Date & Time | 16 OCT 2022 23:59 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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 ☐

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

[Patient Cloud Close Date & Time](#)

23 OCT 2022 23:59

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

| 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"/> |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 26 OCT 2022 00:01 |
| Patient Cloud Close Date & Time | 30 OCT 2022 23:59 |

US3362244

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:14:58

| 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 | | 09 MAR 2021 06:41:46 |

US3362244

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 06 Mar 2021 04:26:37

Generated On: 09 Jun 2021 17:14:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3362244

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 06 Mar 2021 04:26:37

Generated On: 09 Jun 2021 17:14:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362244

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 25 Apr 2021 01:32:37

Generated On: 09 Jun 2021 17:14:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3362244

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 25 Apr 2021 01:32:37

Generated On: 09 Jun 2021 17:14:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362244

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 25 Apr 2021 01:32:37

Generated On: 09 Jun 2021 17:14:58

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

US3362244

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 25 Apr 2021 01:32:37

Generated On: 09 Jun 2021 17:14:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362244

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 25 Apr 2021 01:32:37

Generated On: 09 Jun 2021 17:14:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3362244

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 25 Apr 2021 01:32:37

Generated On: 09 Jun 2021 17:14:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362244

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 25 Apr 2021 01:32:37

Generated On: 09 Jun 2021 17:14:58

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

| | |
|--------------------------|-------------|
| Visit date (dd MMM yyyy) | 10 MAR 2021 |
|--------------------------|-------------|

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

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

US3362244

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:58

| | |
|---|-----------------------------------|
| 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) | |

US3362244

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 25 Apr 2021 01:32:37

Generated On: 09 Jun 2021 17:14:58

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.

US3362244

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 25 Apr 2021 01:32:37

Generated On: 09 Jun 2021 17:14:58

| | |
|------------------------------------|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (dd MMM yyyy) | 10 MAR 2021 |
| Collection time (00:00-23:59) | 10:43 (24 HR) |
| Collection date and time (derived) | 10 MAR 2021 10:43 |

US3362244

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 25 Apr 2021 01:32:37

Generated On: 09 Jun 2021 17:14:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362244

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 25 Apr 2021 01:32:37

Generated On: 09 Jun 2021 17:14:58

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

US3362244

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 25 Apr 2021 01:32:37

Generated On: 09 Jun 2021 17:14:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362244

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:58

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

US3362244

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:14:58

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3362244

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:14:58

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

US3362244

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:14:58

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3362244

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

Form: Visit Date

Data signed: (b) (4) 25 Apr 2021 01:32:36

Generated On: 09 Jun 2021 17:14:58

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

| | |
|--------------------------|------------|
| Visit date (dd MMM yyyy) | 6 JAN 2021 |
|--------------------------|------------|

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

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

US3362244

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

Form: Unblinding

Data signed: (b) (4) 25 Apr 2021 01:32:36

Generated On: 09 Jun 2021 17:14:58

| | |
|---|---|
| Date of updated informed consent (<i>dd MMM yyyy</i>) | 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 (<i>dd MMM yyyy</i>) | 6 JAN 2021 |
| Participant randomization assignment | mRNA-1273 <input checked="" type="radio"/> Placebo <input type="radio"/> |
| Actual Dose 1 | mRNA-1273 <input checked="" type="radio"/> Placebo <input type="radio"/> Not Administered <input type="radio"/> |
| Actual Dose 2 | mRNA-1273 <input type="radio"/> Placebo <input type="radio"/> Not Administered <input checked="" type="radio"/> |
| Will participant receive mRNA-1273? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Placebo Only Flag | |
| Continuing with mRNA-1273 | 1 |

US3362244

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 25 Apr 2021 01:32:36

Generated On: 09 Jun 2021 17:14:58

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

US3362244

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 25 Apr 2021 01:32:36

Generated On: 09 Jun 2021 17:14:58

| | |
|-------------------------------------|--|
| Height | ND - Not Done |
| Weight | ND - Not Done |
| 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) | 6 JAN 2021 |
| Time of assessment (00:00-23:59) | 07:55 (24 HR) |
| Vital Signs Date and Time (derived) | 6 JAN 2021 07:55 |
| 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) | 73 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 12 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 |

US3362244

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 25 Apr 2021 01:32:36

Generated On: 09 Jun 2021 17:14:58

| | |
|-------------------------------------|--|
| Height | ND - Not Done |
| Weight | ND - Not Done |
| 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) | 6 JAN 2021 |
| Time of assessment (00:00-23:59) | 08:55 (24 HR) |
| Vital Signs Date and Time (derived) | 6 JAN 2021 08:55 |
| Temperature (xxx.x) | 36.8 C |
| Route of measurement | Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 67 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 16 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 133 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 85 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3362244

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

Form: Physical Examination

Data signed: (b) (4) 25 Apr 2021 01:32:36

Generated On: 09 Jun 2021 17:14:58

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

6 JAN 2021

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

US3362244

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

Form: Exposure

Data signed: (b) (4) 25 Apr 2021 01:32:36

Generated On: 09 Jun 2021 17:14:58

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) 6 JAN 2021

What was the treatment time? (00:00-23:59) 08:19 (24 HR)

Treatment Date and Time (derived) 6 JAN 2021 08:19

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

US3362244

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 25 Apr 2021 01:32:36

Generated On: 09 Jun 2021 17:14:58

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

| | |
|-------------------------------|------------|
| Collection date (dd MMM yyyy) | 6 JAN 2021 |
|-------------------------------|------------|

| | |
|-------------------------------|---------------|
| Collection time (00:00-23:59) | 07:44 (24 HR) |
|-------------------------------|---------------|

| | |
|------------------------------------|------------------|
| Collection date and time (derived) | 6 JAN 2021 07:44 |
|------------------------------------|------------------|

US3362244

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 25 Apr 2021 01:32:36

Generated On: 09 Jun 2021 17:14:58

| | |
|------------------------------------|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (dd MMM yyyy) | 6 JAN 2021 |
| Collection time (00:00 - 23:59) | 07:45 |
| Collection Date and Time (derived) | 6 JAN 2021 07:45 |

US3362244

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

Form: Continuing

Data signed: (b) (4) 25 Apr 2021 01:32:36

Generated On: 09 Jun 2021 17:14:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362244

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 25 Apr 2021 01:32:37

Generated On: 09 Jun 2021 17:14:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3362244

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 25 Apr 2021 01:32:37

Generated On: 09 Jun 2021 17:14:58

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

US3362244

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 25 Apr 2021 01:32:36

Generated On: 09 Jun 2021 17:14:58

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 3 FEB 2021 |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/> |
| | Clinic <input checked="" type="radio"/> |
| Folder OID | OLD29 |

US3362244

Folder: OL-D29 (1)

Form: Vital Signs

Data signed: (b) (4) 25 Apr 2021 01:32:36

Generated On: 09 Jun 2021 17:14:58

| | |
|---|---------------------------------------|
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (<i>dd MMM yyyy</i>) | 03 FEB 2021 |
| Time of assessment (<i>00:00-23:59</i>) | 10:45 (24 HR) |
| Vital Signs Date and Time (derived) | 03 FEB 2021 10:45 |
| Temperature (<i>xxx.x</i>) | 37.0 C |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (<i>xxx</i>) | 74 beats/min |
| Pulse units | BPM |
| Respiratory Rate (<i>xxx</i>) | 18 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (<i>xxx</i>) | 143 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (<i>xxx</i>) | 86 mmHg |
| Diastolic Blood Pressure units | MMHG |
| Height (derived) | |
| Weight (derived) | |

US3362244

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 25 Apr 2021 01:32:36

Generated On: 09 Jun 2021 17:14:58

| | |
|-------------------------------------|---|
| 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) | 3 FEB 2021 |
| Time of assessment (00:00-23:59) | 10:45 (24 HR) |
| Vital Signs Date and Time (derived) | 3 FEB 2021 10:45 |
| Temperature (xxx.x) | 37.0 C |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 74 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 18 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 143 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 86 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3362244

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 25 Apr 2021 01:32:36

Generated On: 09 Jun 2021 17:14:58

| | |
|---|--|
| Timepoint | Pre-Dose <input type="radio"/> |
| | Post-Dose <input checked="" type="radio"/> |
| Were vital signs assessed? | Yes <input type="radio"/> |
| | No <input checked="" type="radio"/> |
| 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="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| 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 | |

US3362244

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 25 Apr 2021 01:32:36

Generated On: 09 Jun 2021 17:14:58

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.

US3362244

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 25 Apr 2021 01:32:36

Generated On: 09 Jun 2021 17:14:58

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

SUBJECT RECEIVED FIRST DOSE OF MRNA1273 DURING PHASE A AND 2ND DOSE DURING OL-1 VISIT.

What was the study treatment? _____

What was the treatment date? (dd MMM yyyy) _____

What was the treatment time? (00:00-23:59) _____

Treatment Date and Time (derived) _____

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

What was the frequency of the study treatment dosing? _____

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

US3362244

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 25 Apr 2021 01:32:36

Generated On: 09 Jun 2021 17:14:58

| | |
|------------------------------------|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (dd MMM yyyy) | 3 FEB 2021 |
| Collection time (00:00-23:59) | 10:54 (24 HR) |
| Collection date and time (derived) | 3 FEB 2021 10:54 |

US3362244

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 25 Apr 2021 01:32:36

Generated On: 09 Jun 2021 17:14:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362244

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:58

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

US3362244

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:14:58

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3362244

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 13 Mar 2021 22:19:50

Generated On: 09 Jun 2021 17:14:58

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3362244

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 13 Mar 2021 22:19:50

Generated On: 09 Jun 2021 17:14:58

AEID

Adverse event

WORSENING OF LEFT HIP
PAIN/ARTHRITIS

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

08 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

11 NOV 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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EAB) (1725)

US3362244

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 13 Mar 2021 22:19:50

Generated On: 09 Jun 2021 17:14:58

| | |
|--|---|
| Number of Days in ICU | |
| Persistent or significant disability or incapacity | False |
| Congenital anomaly or birth defect | False |
| Other medically important event | False |
| Relationship to investigational product | Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/> |
| Relationship to Study Procedure | Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/> |
| Action taken with investigational product | None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input checked="" type="radio"/> Not Applicable <input 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 | |
| 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) | |

US3362244

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 13 Mar 2021 22:19:50

Generated On: 09 Jun 2021 17:14:58

| | |
|--|--|
| AEID | USA-US112-2020-MRNA-1273-P30 1000006 |
| Adverse event | POST OPERATIVE INTRA-ABDOMINAL ABSCESS |
| 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) | 12 OCT 2020 |
| Start time (00:00-23:59) | |
| AE start date and time (derived) | |
| Ongoing? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| If not Ongoing, end date (dd MMM yyyy) | 13 OCT 2020 |
| End time (00:00-23:59) | |
| AE End Date and Time (derived) | |
| Severity | Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/> |
| Is the adverse event serious? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| AE is serious due To (check all that apply) | |
| Death | False |
| Life threatening | False |
| Requires inpatient or prolongation of existing Hospitalization | True |
| Hospital Admission Date (dd MMM yyyy) | 12 OCT 2020 |
| Hospital Discharge Date (dd MMM yyyy) | 20 OCT 2020 |
| Admitted to ICU? | Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/> |
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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 13 Mar 2021 22:19:50

Generated On: 09 Jun 2021 17:14:58

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

US3362244

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 13 Mar 2021 22:19:50

Generated On: 09 Jun 2021 17:14:58

SUBJECT HAD A PLANNED
PROCEDURE FOR REPAIR OF
LEFT PUBIC RAMI DUE TO
CHRONIC/WORSENING
ARTHRITIS. PROCEDURE WENT
WELL INITIALLY, HOWEVER
ABSCCESS DEVELOPED AND
REQUIRED INPATIENT
HOSPITALIZATION, SUBJECT
NOTIFIED STAFF ON 28OCT2020
REGARDING INPATIENT
TREATMENT

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

US3362244

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 13 Mar 2021 22:19:50

Generated On: 09 Jun 2021 17:14:58

| | |
|--|--|
| AEID | USA-US112-2020-MRNA-1273-P30 1000006 |
| Adverse event | RIGHT AXILLARY DEEP VEIN THROMBOSIS |
| 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) | 19 OCT 2020 |
| Start time (00:00-23:59) | |
| AE start date and time (derived) | |
| Ongoing? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| If not Ongoing, end date (dd MMM yyyy) | 05 NOV 2020 |
| End time (00:00-23:59) | |
| AE End Date and Time (derived) | |
| Severity | Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/> |
| Is the adverse event serious? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| AE is serious due To (check all that apply) | |
| Death | False |
| Life threatening | True |
| 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"/> |
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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 13 Mar 2021 22:19:50

Generated On: 09 Jun 2021 17:14:58

| | |
|--|---|
| Number of Days in ICU | |
| Persistent or significant disability or incapacity | False |
| Congenital anomaly or birth defect | False |
| Other medically important event | False |
| Relationship to investigational product | Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/> |
| Relationship to Study Procedure | Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/> |
| Action taken with investigational product | None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/> |
| Other action taken (check all that apply) | |
| None | False |
| Concomitant Medication | True |
| Concomitant Procedure | 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 | SUBJECT HAD PICC LINE PLACED POST SURGERY, NOTE TO HAVE PAIN ON 10/19/2020 DIAGNOSED WITH DVT AND PICC LINE REMOVED, ON ANTI-COAGULANTS |
| Serious Adverse Event Derived (CSA Programming Field Only) | 1 |

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 13 Mar 2021 22:19:50

Generated On: 09 Jun 2021 17:14:58

| | |
|--|---|
| Medically Attended AE Derived (CSA Programming Field Only) | 1 |
| Admitted to ICU Derived (CSA Programming Field Only) | 0 |

US3362244

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 13 Mar 2021 22:19:50

Generated On: 09 Jun 2021 17:14:58

| | |
|--|--|
| AEID | USA-US112-2020-MRNA-1273-P30 1000007 |
| Adverse event | WORSENING OF ANTERIOR LEFT PELVIC RING NON-UNION |
| 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) | 09 SEP 2020 |
| Start time (00:00-23:59) | |
| AE start date and time (derived) | |
| Ongoing? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| If not Ongoing, end date (dd MMM yyyy) | 05 OCT 2020 |
| End time (00:00-23:59) | |
| AE End Date and Time (derived) | |
| Severity | Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/> |
| Is the adverse event serious? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| AE is serious due To (check all that apply) | |
| Death | False |
| Life threatening | False |
| Requires inpatient or prolongation of existing Hospitalization | True |
| Hospital Admission Date (dd MMM yyyy) | 29 SEP 2020 |
| Hospital Discharge Date (dd MMM yyyy) | 5 OCT 2020 |
| Admitted to ICU? | Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/> |
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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 13 Mar 2021 22:19:50

Generated On: 09 Jun 2021 17:14:58

| | |
|--|---|
| 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 checked="" type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input 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 | PATIENT HAD PLANNED PROCEDURE FOR REPAIR OF ANTERIOR LEFT PELVIC RING, DID NOT DISCLOSE HOSPITALIZATION. |
| Serious Adverse Event Derived (CSA Programming Field Only) | 1 |
| Medically Attended AE Derived (CSA Programming Field Only) | 1 |
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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 13 Mar 2021 22:19:50

Generated On: 09 Jun 2021 17:14:58

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

0

US3362244

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 13 Mar 2021 22:19:50

Generated On: 09 Jun 2021 17:14:58

| | |
|--|--|
| AEID | USA-US112-2020-MRNA-1273-P30 1000006 |
| Adverse event | RIGHT BRACHIAL DEEP VEIN THROMBOSIS |
| 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) | 19 OCT 2020 |
| Start time (00:00-23:59) | |
| AE start date and time (derived) | |
| Ongoing? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| If not Ongoing, end date (dd MMM yyyy) | 05 NOV 2020 |
| End time (00:00-23:59) | |
| AE End Date and Time (derived) | |
| Severity | Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/> |
| Is the adverse event serious? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| AE is serious due To (check all that apply) | |
| Death | False |
| Life threatening | True |
| 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"/> |
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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 13 Mar 2021 22:19:50

Generated On: 09 Jun 2021 17:14:58

| | |
|--|---|
| Number of Days in ICU | |
| Persistent or significant disability or incapacity | False |
| Congenital anomaly or birth defect | False |
| Other medically important event | False |
| Relationship to investigational product | Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/> |
| Relationship to Study Procedure | Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/> |
| Action taken with investigational product | None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/> |
| Other action taken (check all that apply) | |
| None | False |
| Concomitant Medication | True |
| Concomitant Procedure | 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 | SUBJECT HAD PICC LINE PLACED POST SURGERY, NOTE TO HAVE PAIN ON 10/19/2020 DIAGNOSED WITH DVT AND PICC LINE REMOVED, ON ANTI-COAGULANTS |
| Serious Adverse Event Derived (CSA Programming Field Only) | 1 |

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 13 Mar 2021 22:19:50

Generated On: 09 Jun 2021 17:14:58

| | |
|--|---|
| Medically Attended AE Derived (CSA Programming Field Only) | 1 |
| Admitted to ICU Derived (CSA Programming Field Only) | |

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 13 Mar 2021 22:19:50

Generated On: 09 Jun 2021 17:14:58

AEID

Adverse event

DIARRHEA

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

29 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

12 NOV 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (6)

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

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 13 Mar 2021 22:19:50

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AEID

Adverse event

MACULAR RASH
NON-URTICARIAL
(GENERALIZED)

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

11 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

18 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 13 Mar 2021 22:19:50

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| | |
|--|---|
| Number of Days in ICU | |
| Persistent or significant disability or incapacity | False |
| Congenital anomaly or birth defect | False |
| Other medically important event | False |
| Relationship to investigational product | Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/> |
| Relationship to Study Procedure | Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/> |
| Action taken with investigational product | None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/> |
| Other action taken (check all that apply) | |
| None | 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) | 0 |
| Admitted to ICU Derived (CSA Programming Field Only) | |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 09 Apr 2021 00:58:08

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 09 Apr 2021 00:58:07

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Name of Medication ALENDRONATE

Prophylaxis Yes ☐
No ☒

Indication OSTEOPOROSIS

Dose per administration 70

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)

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| | | |
|--|--------------------------|----------------------------------|
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | UN UNK 2019 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | 1 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input checked="" type="radio"/> |
| | 804 | <input type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 09 Apr 2021 00:58:07

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Name of Medication ATORVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 80

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) 09 Apr 2021 00:58:07

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| | | |
|--|--------------------------|-------------------------------------|
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | UN UNK 2015 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) | 3 NOV 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 (4)

Data signed: (b) (4) 09 Apr 2021 00:58:07

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Name of Medication TYLENOL ARTHRITIS

Prophylaxis Yes ☐
No ☒

Indication OSTEOARTHRITIS

Dose per administration 650

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

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| | | |
|--|--------------------------|----------------------------------|
| | 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 (5)

Data signed: (b) (4) 09 Apr 2021 00:58:07

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Name of Medication TYLENOL EXTRA STRENGTH

Prophylaxis Yes ☐
No ☒

Indication OSTEOARTHRITIS

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

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| | | |
|--|--------------------------|-------------------------------------|
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | 25 AUG 2020 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) | | 27 AUG 2020 |
| Was this medication taken for solicited event? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived) _____ | | |
| Interval Dosage Unit Number (derived) _____ | | |
| Interval Dosage Definition (derived) | 802 | <input type="checkbox"/> |
| | 803 | <input type="checkbox"/> |
| | 804 | <input type="checkbox"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 09 Apr 2021 00:58:07

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Name of Medication TRAMADOL

Prophylaxis Yes ☐
No ☒

Indication OSTEOARTHRITIS

Dose per administration 25

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 ☐

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Form: Prior/Concomitant Medication and Vaccination (6)

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| | | |
|--|--------------------------|-------------------------------------|
| | 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 FEB 2020 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) | | 3 NOV 2020 |
| Was this medication taken for solicited event? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived) _____ | | |
| Interval Dosage Unit Number (derived) _____ | | |
| Interval Dosage Definition (derived) | 802 | <input type="checkbox"/> |
| | 803 | <input type="checkbox"/> |
| | 804 | <input type="checkbox"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 09 Apr 2021 00:58:07

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Name of Medication HYDROCODONE/ACETAMINOP
HEN

Prophylaxis Yes ☐
No ☒

Indication PAIN SECONDARY WORSENING
OF ANTERIOR LEFT PELVIC
RING NON-UNION

Dose per administration 7.5/325

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

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| | | |
|--|--------------------------|-------------------------------------|
| | Transdermal | <input type="checkbox"/> |
| | 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) | 22 SEP 2020 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) | 3 NOV 2020 | |
| Was this medication taken for solicited event? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived) | 4 | |
| 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 (8)

Data signed: (b) (4) 09 Apr 2021 00:58:07

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Name of Medication METHYLPREDNISOLONE

Prophylaxis Yes ☐
No ☒

Indication PAIN/ HIP FRACTURE

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

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| | | |
|--|--------------------------------------|--------------------------|
| | 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) | 9 SEP 2020 | |
| Start date completely unknown | False | |
| Ongoing? | Yes <input type="checkbox"/> | |
| | No <input checked="" type="radio"/> | |
| If not Ongoing, End date (dd MMM yyyy) | 13 SEP 2020 | |
| Was this medication taken for solicited event? | Yes <input type="checkbox"/> | |
| | No <input checked="" type="radio"/> | |
| 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="radio"/> | |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 09 Apr 2021 00:58:07

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Name of Medication GABAPENTIN

Prophylaxis Yes ☐
No ☒

Indication WORSENING OF ANTERIOR
LEFT PELVIC RING NON-UNION

Dose per administration 100

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

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| | | |
|--|--------------------------|-------------------------------------|
| | 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) | 9 SEP 2020 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) | 3 NOV 2020 | |
| Was this medication taken for solicited event? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived) | 3 | |
| 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 (10)

Data signed: (b) (4) 09 Apr 2021 00:58:07

Generated On: 09 Jun 2021 17:14:58

Name of Medication DULCOLAX

Prophylaxis Yes ☒
No ☐

Indication HELP PREVENT CONSTIPATION
FROM PAIN MEDICATION

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 09 Apr 2021 00:58:07

Generated On: 09 Jun 2021 17:14:58

| | | |
|--|--------------------------|-------------------------------------|
| | 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) | 22 SEP 2020 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) | 29 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"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 09 Apr 2021 00:58:07

Generated On: 09 Jun 2021 17:14:58

Name of Medication APIXABAN

Prophylaxis Yes ☐
No ☒

Indication RIGHT AXILLARY AND
BRACHIAL DEEP VEIN
THROMBOSIS

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 09 Apr 2021 00:58:07

Generated On: 09 Jun 2021 17:14:58

| | | |
|--|--------------------------|-------------------------------------|
| | 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) | 20 OCT 2020 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) | | 20 NOV 2020 |
| Was this medication taken for solicited event? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived) | 2 | |
| 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 (12)

Data signed: (b) (4) 09 Apr 2021 00:58:07

Generated On: 09 Jun 2021 17:14:58

Name of Medication DICLOFENAC EC

Prophylaxis Yes ☐
No ☒

Indication LEFT HIP PAIN DUE TO
WORSENING OF ANTERIOR
LEFT PELVIC RING NON-UNION

Dose per administration 50

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 ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 09 Apr 2021 00:58:07

Generated On: 09 Jun 2021 17:14:58

| | | |
|--|--------------------------|-------------------------------------|
| | 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) | 20 OCT 2020 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) | | 3 NOV 2020 |
| Was this medication taken for solicited event? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived) _____ | | |
| Interval Dosage Unit Number (derived) _____ | | |
| Interval Dosage Definition (derived) | 802 | <input type="checkbox"/> |
| | 803 | <input type="checkbox"/> |
| | 804 | <input type="checkbox"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 09 Apr 2021 00:58:07

Generated On: 09 Jun 2021 17:14:58

Name of Medication RIFAMPIN

Prophylaxis Yes ☐
No ☒

Indication POST OPERATIVE
INTRA-ABDOMINAL ABSCESS

Dose per administration 300

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 09 Apr 2021 00:58:07

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| | | |
|--|--------------------------|-------------------------------------|
| | 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) | 20 OCT 2020 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) | 3 NOV 2020 | |
| Was this medication taken for solicited event? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived) | 2 | |
| 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 (14)

Data signed: (b) (4) 09 Apr 2021 00:58:07

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Name of Medication ANCEF

Prophylaxis Yes ☐
No ☒

Indication POST OPERATIVE
INTRA-ABDOMINAL ABSCESS

Dose per administration 2

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 09 Apr 2021 00:58:07

Generated On: 09 Jun 2021 17:14:58

| | | |
|--|--------------------------|-------------------------------------|
| | 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 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) | 20 OCT 2020 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) | 3 NOV 2020 | |
| Was this medication taken for solicited event? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived) | 3 | |
| 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 (15)

Data signed: (b) (4) 09 Apr 2021 00:58:07

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Name of Medication FERROUS SULFATE

Prophylaxis Yes ☐
No ☒

Indication ALPHA THALASSEMIA

Dose per administration 324

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 (15)

Data signed: (b) (4) 09 Apr 2021 00:58:07

Generated On: 09 Jun 2021 17:14:58

| | | |
|--|--------------------------|----------------------------------|
| | 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) | 20 OCT 2020 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | 1 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 09 Apr 2021 00:58:07

Generated On: 09 Jun 2021 17:14:58

Name of Medication LACTATED RINGERS

Prophylaxis Yes ☐
No ☒

Indication IV HYDRATION SECONDARY
TO POST OPERATIVE
INTRA-ABDOMINAL ABSCESS

Dose per administration 1000

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 ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 09 Apr 2021 00:58:07

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| | | |
|--|--------------------------|-------------------------------------|
| | 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 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) | | 12 OCT 2020 |
| Start date completely unknown | | False |
| Ongoing? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) | | 12 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"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 09 Apr 2021 00:58:07

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Name of Medication LINEZOLID

Prophylaxis Yes ☐
No ☒

Indication POST-OPERATIVE
INTRABDOMINAL ABSCESS

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 09 Apr 2021 00:58:07

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| | | |
|--|--------------------------|-------------------------------------|
| | 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) | 4 NOV 2020 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) | 13 NOV 2020 | |
| Was this medication taken for solicited event? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived) | 2 | |
| 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 (18)

Data signed: (b) (4) 09 Apr 2021 00:58:07

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Name of Medication DAPTOMYCIN

Prophylaxis Yes ☐
No ☒

Indication POST OPERATIVE
INTRABDOMINAL ABSCESS

Dose per administration 420

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 09 Apr 2021 00:58:07

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| | | |
|--|--------------------------|-------------------------------------|
| | 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 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) | 9 NOV 2020 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) | 19 NOV 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 (19)

Data signed: (b) (4) 09 Apr 2021 00:58:07

Generated On: 09 Jun 2021 17:14:58

Name of Medication CALCIUM

Prophylaxis Yes ☐
No ☒

Indication OSTEOPOROSIS

Dose per administration 500

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 (19)

Data signed: (b) (4) 09 Apr 2021 00:58:07

Generated On: 09 Jun 2021 17:14:58

| | | |
|--|--------------------------|----------------------------------|
| | 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) | 13 NOV 2020 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | 2 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 09 Apr 2021 00:58:07

Generated On: 09 Jun 2021 17:14:58

Name of Medication PROLIA

Prophylaxis Yes ☐
No ☒

Indication OSTEOPOROSIS

Dose per administration 60

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 MONTHS

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

PRODUCTION RELEASE (v12.003

385 of 2497

EAB) (1725)

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 09 Apr 2021 00:58:07

Generated On: 09 Jun 2021 17:14:58

| | | |
|--|--------------------------|-------------------------------------|
| | 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) | | 05 NOV 2020 |
| Start date completely unknown | | False |
| Ongoing? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) 05 NOV 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"/> |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 09 Apr 2021 00:58:07

Generated On: 09 Jun 2021 17:14:58

Name of Medication DOXYCYCLINE HYC

Prophylaxis Yes ☒
No ☐

Indication JOINT INFECTION
PROPHYLAXIS - SUPPRESSION
ANTIBIOTICS

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

387 of 2497

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 09 Apr 2021 00:58:07

Generated On: 09 Jun 2021 17:14:58

| | | |
|--|--------------------------|----------------------------------|
| | 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) | | 24 NOV 2020 |
| Start date completely unknown | | False |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | | 2 |
| Interval Dosage Unit Number (derived) | | 1 |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

US3362244

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 09 Apr 2021 00:58:08

Generated On: 09 Jun 2021 17:14:58

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3362244

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 09 Apr 2021 00:58:08

Generated On: 09 Jun 2021 17:14:58

| Procedure/Surgery date (dd MMM yyyy) | Procedure/Surgery | Indication | If indication is Other, specify |
|---|--|---------------|---------------------------------|
| 13 OCT 2020 | DRAINAGE OF ABSCESS | Adverse Event | |
| 29 SEP 2020 | LEFT PELVIC RING FRACTURE NONUNION REPAIR | Adverse Event | |
| 20 OCT 2020 | PICC LINE PLACEMENT LEFT ARM | Adverse Event | |
| 18 OCT 2020 | PICC LINE PLACEMENT RIGHT ARM | Adverse Event | |

US3362244

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 25 Apr 2021 01:32:36

Generated On: 09 Jun 2021 17:14:58

| | |
|--|-------------|
| Date of dosing discontinuation (dd MMM yyyy) | 23 SEP 2020 |
|--|-------------|

| | |
|---|--|
| Primary reason for dosing discontinuation | AE (specify) <input checked="" type="radio"/> |
| | SAE (specify) <input type="radio"/> |
| | Death <input type="radio"/> |
| | Lost To Follow-up <input type="radio"/> |
| | Physician decision (specify) <input type="radio"/> |
| | Pregnancy <input type="radio"/> |
| | Protocol deviation (specify) <input type="radio"/> |
| | Study Terminated By Sponsor <input type="radio"/> |
| | Withdrawal of consent by participant (specify) <input type="radio"/> |
| | Due to SARS-COV-2 <input type="radio"/> |
| | Other <input type="radio"/> |

| | |
|---|----------------------------|
| If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify | AE # 2, AE # 3, AND AE # 5 |
|---|----------------------------|

US3362244

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) 25 Apr 2021 01:32:36

Generated On: 09 Jun 2021 17:14:58

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 ☐

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Data signed: (b) (4) 25 Apr 2021 01:32:36

Generated On: 09 Jun 2021 17:14:58

| | |
|--|--|
| SAEID | USA-US112-2020-MRNA-1273-P301000006 |
| Serious | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening | Yes <input checked="" type="radio"/> No <input 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 | JORDAN |
| Investigator's Last Name | WHATLEY |
| Site Address: Street | 5326 O'DONOVAN DR |
| Site Address: City | BATON ROUGE |
| Site Address: State | |
| Site Address: Postal Code | 70808 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 5 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Data signed: (b) (4) 25 Apr 2021 01:32:36

Generated On: 09 Jun 2021 17:14:58

| | |
|---|--|
| SAEID | USA-US112-2020-MRNA-1273-P301000006 |
| Serious | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening | Yes <input checked="" type="radio"/> No <input 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 | JORDAN |
| Investigator's Last Name | WHATLEY |
| Site Address: Street | 5326 O'DONOVAN DR |
| Site Address: City | BATON ROUGE |
| Site Address: State | |
| Site Address: Postal Code | 70808 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 5 |
| Date of submission (Pre-filled from custom function) | 29/OCT/2020 18:59 |
| 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 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form (2)

Data signed: (b) (4) 25 Apr 2021 01:32:36

Generated On: 09 Jun 2021 17:14:58

| | |
|---|--|
| SAEID | USA-US112-2020-MRNA-1273-P301000006 |
| Serious | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening | Yes <input checked="" type="radio"/> No <input 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 | JORDAN |
| Investigator's Last Name | WHATLEY |
| Site Address: Street | 5326 O'DONOVAN DR |
| Site Address: City | BATON ROUGE |
| Site Address: State | |
| Site Address: Postal Code | 70808 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 5 |
| Date of submission (Pre-filled from custom function) | 30/OCT/2020 13:55 |
| 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. | False |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form (3)

Data signed: (b) (4) 25 Apr 2021 01:32:36

Generated On: 09 Jun 2021 17:14:58

| | |
|---|--|
| SAEID | USA-US112-2020-MRNA-1273-P301000006 |
| Serious | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening | Yes <input checked="" type="radio"/> No <input 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 | JORDAN |
| Investigator's Last Name | WHATLEY |
| Site Address: Street | 5326 O'DONOVAN DR |
| Site Address: City | BATON ROUGE |
| Site Address: State | |
| Site Address: Postal Code | 70808 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 5 |
| Date of submission (Pre-filled from custom function) | 02/NOV/2020 10:04 |
| 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 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form (4)

Data signed: (b) (4) 25 Apr 2021 01:32:36

Generated On: 09 Jun 2021 17:14:58

| | |
|---|--|
| SAEID | USA-US112-2020-MRNA-1273-P301000006 |
| Serious | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening | Yes <input checked="" type="radio"/> No <input 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 | JORDAN |
| Investigator's Last Name | WHATLEY |
| Site Address: Street | 5326 O'DONOVAN DR |
| Site Address: City | BATON ROUGE |
| Site Address: State | |
| Site Address: Postal Code | 70808 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 5 |
| Date of submission (Pre-filled from custom function) | 11/NOV/2020 19:08 |
| 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 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form (5)

Data signed: (b) (4) 25 Apr 2021 01:32:36

Generated On: 09 Jun 2021 17:14:58

| | |
|---|--|
| SAEID | USA-US112-2020-MRNA-1273-P301000006 |
| Serious | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening | Yes <input checked="" type="radio"/> No <input 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 | JORDAN |
| Investigator's Last Name | WHATLEY |
| Site Address: Street | 5326 O'DONOVAN DR |
| Site Address: City | BATON ROUGE |
| Site Address: State | |
| Site Address: Postal Code | 70808 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 5 |
| Date of submission (Pre-filled from custom function) | 15/DEC/2020 10:27 |
| 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 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form (6)

Data signed: (b) (4) 25 Apr 2021 01:32:36

Generated On: 09 Jun 2021 17:14:58

| | |
|---|--|
| SAEID | USA-US112-2020-MRNA-1273-P301000006 |
| Serious | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening | Yes <input checked="" type="radio"/> No <input 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 | JORDAN |
| Investigator's Last Name | WHATLEY |
| Site Address: Street | 5326 O'DONOVAN DR |
| Site Address: City | BATON ROUGE |
| Site Address: State | |
| Site Address: Postal Code | 70808 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 5 |
| Date of submission (Pre-filled from custom function) | 07/JAN/2021 20:00 |
| 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 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Data signed: (b) (4) 25 Apr 2021 01:32:37

Generated On: 09 Jun 2021 17:14:58

| | |
|--|--|
| SAEID | USA-US112-2020-MRNA-1273-P301000007 |
| 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 | JORDAN |
| Investigator's Last Name | WHATLEY |
| Site Address: Street | 5326 O'DONOVAN DR |
| Site Address: City | BATON ROUGE |
| Site Address: State | |
| Site Address: Postal Code | 70808 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 6 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form (1)

Data signed: (b) (4) 25 Apr 2021 01:32:37

Generated On: 09 Jun 2021 17:14:58

| | |
|---|--|
| SAEID | USA-US112-2020-MRNA-1273-P301000007 |
| 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 | JORDAN |
| Investigator's Last Name | WHATLEY |
| Site Address: Street | 5326 O'DONOVAN DR |
| Site Address: City | BATON ROUGE |
| Site Address: State | |
| Site Address: Postal Code | 70808 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 6 |
| Date of submission (Pre-filled from custom function) | 02/NOV/2020 10:04 |
| 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 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form (2)

Data signed: (b) (4) 25 Apr 2021 01:32:37

Generated On: 09 Jun 2021 17:14:58

| | |
|---|--|
| SAEID | USA-US112-2020-MRNA-1273-P301000007 |
| 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 | JORDAN |
| Investigator's Last Name | WHATLEY |
| Site Address: Street | 5326 O'DONOVAN DR |
| Site Address: City | BATON ROUGE |
| Site Address: State | |
| Site Address: Postal Code | 70808 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 6 |
| Date of submission (Pre-filled from custom function) | 10/NOV/2020 11:32 |
| Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge. | True |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form (3)

Data signed: (b) (4) 25 Apr 2021 01:32:37

Generated On: 09 Jun 2021 17:14:58

| | |
|---|--|
| SAEID | USA-US112-2020-MRNA-1273-P301000007 |
| 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 | JORDAN |
| Investigator's Last Name | WHATLEY |
| Site Address: Street | 5326 O'DONOVAN DR |
| Site Address: City | BATON ROUGE |
| Site Address: State | |
| Site Address: Postal Code | 70808 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 6 |
| Date of submission (Pre-filled from custom function) | 11/NOV/2020 20:31 |
| Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge. | True |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form (4)

Data signed: (b) (4) 25 Apr 2021 01:32:37

Generated On: 09 Jun 2021 17:14:58

| | |
|---|--|
| SAEID | USA-US112-2020-MRNA-1273-P301000007 |
| 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 | JORDAN |
| Investigator's Last Name | WHATLEY |
| Site Address: Street | 5326 O'DONOVAN DR |
| Site Address: City | BATON ROUGE |
| Site Address: State | |
| Site Address: Postal Code | 70808 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 6 |
| Date of submission (Pre-filled from custom function) | 13/NOV/2020 13:41 |
| 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 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form (5)

Data signed: (b) (4) 25 Apr 2021 01:32:37

Generated On: 09 Jun 2021 17:14:58

| | |
|---|--|
| SAEID | USA-US112-2020-MRNA-1273-P301000007 |
| 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 | JORDAN |
| Investigator's Last Name | WHATLEY |
| Site Address: Street | 5326 O'DONOVAN DR |
| Site Address: City | BATON ROUGE |
| Site Address: State | |
| Site Address: Postal Code | 70808 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 6 |
| Date of submission (Pre-filled from custom function) | 20/NOV/2020 19:28 |
| 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 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form (6)

Data signed: (b) (4) 25 Apr 2021 01:32:37

Generated On: 09 Jun 2021 17:14:58

| | |
|---|--|
| SAEID | USA-US112-2020-MRNA-1273-P301000007 |
| 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 | JORDAN |
| Investigator's Last Name | WHATLEY |
| Site Address: Street | 5326 O'DONOVAN DR |
| Site Address: City | BATON ROUGE |
| Site Address: State | |
| Site Address: Postal Code | 70808 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 6 |
| Date of submission (Pre-filled from custom function) | 16/DEC/2020 13:55 |
| 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

US3362244 (Prod: Meridian Clinical Research-(Baton Rouge, Louisiana) - Platinum - PPDS)

US3362244

Form: Participant Creation

Generated On: 09 Jun 2021 17:14:58

[Participant ID](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| User entered 'US3362244' | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 24 Aug 2020 18:39:16 |

US3362244

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:14:58

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 24 Aug 2020 20:13:55 |

US3362244

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered '24 AUG 2020' | RWS_ENDPOINT ENDPOINT (b) (4) | 24 Aug 2020 18:39:17 |

US3362244

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:14:58

[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 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered 'Clinic (Clinic)' | (b) (4) (b) (4), (b) (6) | 24 Aug 2020 20:13:55 |

US3362244

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:14:58

[Folder OID](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User entered 'SCRN' | System | 24 Aug 2020 20:13:55 |

US3362244

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered (b) (6) 1954' | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 24 Aug 2020 18:39:19 |

US3362244

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:14:58

[Age](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered '66' | (b) (4) (b) (4), (b) (6) | 24 Aug 2020 20:14:16 |

US3362244

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:14:58

[Age Units](#)

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User entered 'YEARS' | System | 24 Aug 2020 20:14:16 |

US3362244

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:14:58

[Age \(Derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User entered '66' | System | 24 Aug 2020 20:14:37 |

US3362244

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:14:58

[Sex](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered 'Female (F)' | (b) (4) (b) (4), (b) (6) | 24 Aug 2020 20:14:16 |

US3362244

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:14:58

[Ethnicity](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)' | (b) (4), (b) (6) | 24 Aug 2020 20:14:16 |

US3362244

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:14:58

[White](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered 'I' | (b) (4), (b) (6) | 24 Aug 2020 20:14:16 |

US3362244

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:14:58

[Black](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered '0' | (b) (4), (b) (6) | 24 Aug 2020 20:14:16 |

US3362244

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:14:58

[Asian](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered '0' | (b) (4), (b) (6) | 24 Aug 2020 20:14:16 |

US3362244

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:14:58

[American Indian or Alaska Native](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered '0' | (b) (4), (b) (6) | 24 Aug 2020 20:14:16 |

US3362244

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:14:58

[Native Hawaiian or other Pacific Islander](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered '0' | (b) (4), (b) (6) | 24 Aug 2020 20:14:16 |

US3362244

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:14:58

[Other](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered '0' | (b) (4), (b) (6) | 24 Aug 2020 20:14:16 |

US3362244

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:14:58

[If race is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 24 Aug 2020 20:14:16 |

US3362244

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:14:58

[Unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered '0' | (b) (4), (b) (6) | 24 Aug 2020 20:14:16 |

US3362244

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:14:58

[Not reported](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 24 Aug 2020 20:14:16 |

US3362244

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:14:58

Date of Informed Consent (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered '24 Aug 2020' | (b) (4) (b) (4), (b) (6) | 24 Aug 2020 20:14:37 |

US3362244

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User entered 'Aug 2020' | System | 24 Aug 2020 20:14:37 |

US3362244

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User entered '2020' | System | 24 Aug 2020 20:14:37 |

US3362244

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:14:58

[Protocol Version](#)

| Audit | User | Time (GMT) |
|--------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered 'Amendment 2 (2)' | (b) (4), (b) (6) | 24 Aug 2020 20:14:37 |

US3362244

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 24 Aug 2020 20:14:37 |

US3362244

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 24 Aug 2020 20:14:37 |

US3362244

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:14:58

If reason for screen fail is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 24 Aug 2020 20:14:37 |

US3362244

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:14:58

[Was this participant screened previously?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 24 Aug 2020 20:14:37 |

US3362244

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:14:58

[If Yes, previous participant number](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered empty. | RWS_ENDPOINT ENDPOINT (b) (4) | 24 Aug 2020 18:39:17 |

US3362244

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:14:58

[Enrollment Trigger](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User entered 'I' | System | 24 Aug 2020 20:14:41 |

US3362244

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 24 Aug 2020 20:14:41 |

US3362244

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:14:58

[Were any significant conditions reported?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 25 Aug 2020 14:49:17 |

US3362244

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:14:58

[Condition](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Bone disorders (excl congenital and fractures), HLT: Metabolic bone disorders, PT: Osteoporosis, LLT: Osteoporosis - version MedDRA\\23.0. | Coder Import (b) (4) | 25 Aug 2020 14:51:33 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 25 Aug 2020 14:51:33 |
| Data point term sent to Coder | System | 25 Aug 2020 14:50:20 |
| User entered 'Osteoporosis' | (b) (4), (b) (6) | 25 Aug 2020 14:50:01 |

US3362244

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered 'un UNK 2010' | (b) (4), (b) (6) | 25 Aug 2020 14:50:01 |

US3362244

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:14:58

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered '0' | (b) (4), (b) (6) | 25 Aug 2020 14:50:01 |

US3362244

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:14:58

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 25 Aug 2020 14:50:01 |

US3362244

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered empty. | (b) (4), (b) (6) | 25 Aug 2020 14:50:01 |

US3362244

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:14:58

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered '0' | (b) (4), (b) (6) | 25 Aug 2020 14:50:01 |

US3362244

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User entered 'Jan 2010' | System | 25 Aug 2020 14:50:01 |

US3362244

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User entered '2010' | System | 25 Aug 2020 14:50:01 |

US3362244

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User entered empty. | System | 25 Aug 2020 14:50:01 |

US3362244

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User entered empty. | System | 25 Aug 2020 14:50:01 |

US3362244

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:14:58

[Condition](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0. | Coder Import (b) (4) | 25 Aug 2020 14:52:39 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 25 Aug 2020 14:52:39 |
| Data point term sent to Coder | System | 25 Aug 2020 14:51:20 |
| User entered 'Hyperlipidemia' | (b) (4), (b) (6) | 25 Aug 2020 14:50:23 |

US3362244

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered 'un UNK 2015' | (b) (4), (b) (6) | 25 Aug 2020 14:50:23 |

US3362244

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:14:58

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered '0' | (b) (4), (b) (6) | 25 Aug 2020 14:50:23 |

US3362244

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:14:58

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 25 Aug 2020 14:50:23 |

US3362244

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered empty. | (b) (4), (b) (6) | 25 Aug 2020 14:50:23 |

US3362244

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:14:58

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered '0' | (b) (4), (b) (6) | 25 Aug 2020 14:50:23 |

US3362244

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User entered 'Jan 2015' | System | 25 Aug 2020 14:50:23 |

US3362244

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User entered '2015' | System | 25 Aug 2020 14:50:23 |

US3362244

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User entered empty. | System | 25 Aug 2020 14:50:23 |

US3362244

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User entered empty. | System | 25 Aug 2020 14:50:23 |

US3362244

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:14:58

Condition

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Bone and joint injuries, HLT: Pelvic fractures and dislocations, PT: Pelvic fracture, LLT: Fracture of pelvis - version MedDRA\23.0. | Coder Import (b) (4) | 17 Dec 2020 12:34:48 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0. | Coder Import (b) (4) | 17 Dec 2020 12:34:48 |
| Data point term sent to Coder | System | 16 Dec 2020 17:06:40 |
| Coding entries removed. | Crystal Rowell (b) (4) | 16 Dec 2020 17:06:26 |
| User entered 'FRACTURED PELVIS (left pelvic ring non-union)' reason for change: Data Entry Error | Crystal Rowell (b) (4) | 16 Dec 2020 17:06:26 |
| Query 'Per DM CLR: Please review the status of this MH as the duration is unexpected for this condition. This condition typically should have the same start/stop date. Please correct dates or provide explanation for the Med History duration. ' canceled (Site from DM). | (b) (4), (b) (6) | 24 Sep 2020 04:31:52 |
| User opened query 'Per DM CLR: Please review the status of this MH as the duration is unexpected for this condition. This condition typically should have the same start/stop date. Please correct dates or provide explanation for the Med History duration. ' (Site from DM). | (b) (4), (b) (6) | 24 Sep 2020 04:31:24 |
| User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Bone and joint injuries, HLT: Pelvic fractures and dislocations, PT: Pelvic fracture, LLT: Fracture of pelvis - version MedDRA\23.0. | Coder Import (b) (4) | 25 Aug 2020 14:52:39 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0. | Coder Import (b) (4) | 25 Aug 2020 14:52:39 |
| Data point term sent to Coder | System | 25 Aug 2020 14:51:20 |
| User entered 'Fractured pelvis' | (b) (4), (b) (6) | 25 Aug 2020 14:50:48 |

US3362244

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:14:58

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User closed query 'Per CDM CLR re-query: Query answer states that condition is not ongoing, however ongoing is answered as YES: Please provide proper end date. Thank you!' (Site from DM). | (b) (4), (b) (6) | 25 Jan 2021 18:02:40 |
| Query 'Per CDM CLR re-query: Query answer states that condition is not ongoing, however ongoing is answered as YES: Please provide proper end date. Thank you!' answered with 'per query for AE#4, site was asked to remove stop date and list this medical history condition as ongoing.' (Site from DM). | Amy Thomassie (b) (4) | 23 Jan 2021 20:02:00 |
| User opened query 'Per CDM CLR re-query: Query answer states that condition is not ongoing, however ongoing is answered as YES: Please provide proper end date. Thank you!' (Site from DM). | (b) (4), (b) (6) | 22 Jan 2021 12:33:58 |
| User closed query 'Per DM CLR: Please review the status of this MH as the duration is unexpected for this condition. This condition typically should have the same start/stop date. Please correct dates or provide explanation for the Med History duration.' (Site from DM). | (b) (4), (b) (6) | 08 Oct 2020 19:07:46 |
| Query 'Per DM CLR: Please review the status of this MH as the duration is unexpected for this condition. This condition typically should have the same start/stop date. Please correct dates or provide explanation for the Med History duration.' answered with 'condition is not ongoing' (Site from DM). | (b) (4), (b) (6) | 25 Sep 2020 13:36:26 |
| User opened query 'Per DM CLR: Please review the status of this MH as the duration is unexpected for this condition. This condition typically should have the same start/stop date. Please correct dates or provide explanation for the Med History duration.' (Site from DM). | (b) (4), (b) (6) | 24 Sep 2020 04:32:07 |
| User entered 'un Feb 2020' | (b) (4), (b) (6) | 25 Aug 2020 14:50:48 |

US3362244

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:14:58

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered '0' | (b) (4), (b) (6) | 25 Aug 2020 14:50:48 |

US3362244

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:14:58

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | (b) (4) | 12 Jan 2021 21:40:07 |
| User entered 'No (N)' | Amy Thomassie (b) (4) | 25 Aug 2020 14:50:48 |
| | (b) (4), (b) (6) | |

US3362244

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered empty; reason for change Data Entry Error | Amy Thomassie (b) (4) | 12 Jan 2021 21:40:07 |
| User closed query 'Per CDM CR: Please review the stop date of this MH as the duration is unexpected for this medical condition. The effects of FRACTURED PELVIS may be ongoing or with a longer duration but the event itself is not. Please correct dates or provide explanation for the Med History duration. ' (Site from DM). | (b) (4), (b) (6) | 27 Oct 2020 18:32:32 |
| Query 'Per CDM CR: Please review the stop date of this MH as the duration is unexpected for this medical condition. The effects of FRACTURED PELVIS may be ongoing or with a longer duration but the event itself is not. Please correct dates or provide explanation for the Med History duration. ' answered with 'updated' (Site from DM). | (b) (4), (b) (6) | 26 Oct 2020 20:40:36 |
| User entered 'UN Apr 2020' reason for change: Data Entry Error | (b) (4), (b) (6) | 26 Oct 2020 20:40:25 |
| User entered 'UN Feb 2020' reason for change: Data Entry Error | (b) (4), (b) (6) | 22 Oct 2020 21:41:26 |
| User opened query 'Per CDM CR: Please review the stop date of this MH as the duration is unexpected for this medical condition. The effects of FRACTURED PELVIS may be ongoing or with a longer duration but the event itself is not. Please correct dates or provide explanation for the Med History duration. ' (Site from DM). | (b) (4), (b) (6) | 20 Oct 2020 17:06:42 |
| User entered 'un Apr 2020' | (b) (4), (b) (6) | 25 Aug 2020 14:50:48 |

US3362244

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:14:58

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered '0' | (b) (4), (b) (6) | 25 Aug 2020 14:50:48 |

US3362244

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User entered 'Feb 2020' | System | 25 Aug 2020 14:50:48 |

US3362244

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User entered '2020' | System | 25 Aug 2020 14:50:48 |

US3362244

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User entered empty. | System | 12 Jan 2021 21:40:07 |
| User entered 'Apr 2020' | System | 26 Oct 2020 20:40:25 |
| User entered 'Feb 2020' | System | 22 Oct 2020 21:41:26 |
| User entered 'Apr 2020' | System | 25 Aug 2020 14:50:48 |

US3362244

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User entered empty. | System | 12 Jan 2021 21:40:07 |
| User entered '2020' | System | 25 Aug 2020 14:50:48 |

US3362244

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:14:58

Condition

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User closed query 'Per CDM (DM CLR RQ): Site response noted. Please ensure the location of osteoarthritis is recorded in the eCRF. ' (Site from DM). | (b) (4) (b) (4), (b) (6) | 04 Nov 2020 12:09:48 |
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Hand osteoarthritis - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 03 Nov 2020 17:07:22 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 03 Nov 2020 17:07:22 |
| Data point term sent to Coder | System | 03 Nov 2020 17:06:27 |
| Query 'Per CDM (DM CLR RQ): Site response noted. Please ensure the location of osteoarthritis is recorded in the eCRF. ' answered with 'updated' (Site from DM). | (b) (4), (b) (6) | 03 Nov 2020 17:06:16 |
| Coding entries removed. | (b) (4), (b) (6) | 03 Nov 2020 17:06:12 |
| User entered 'OSTEOARTHRITIS Bilateral hands' reason for change: Data Entry Error | | 03 Nov 2020 17:06:12 |
| User opened query 'Per CDM (DM CLR RQ): Site response noted. Please ensure the location of osteoarthritis is recorded in the eCRF. ' (Site from DM). | | 03 Nov 2020 15:50:37 |
| User closed query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid, Osteoarthritis, etc.) and the location. 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) | 03 Nov 2020 15:50:37 |
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 30 Oct 2020 16:36:55 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 30 Oct 2020 16:36:55 |

US3362244

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:14:58

Condition

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid, Osteoarthritis, etc.) and the location. 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 'updated' (Site from DM). | (b) (4), (b) (6) | 30 Oct 2020 16:36:27 |
| Data point term sent to Coder | System | 30 Oct 2020 16:36:21 |
| Coding entries removed. | (b) (4), (b) (6) | 30 Oct 2020 16:36:20 |
| User entered 'OSTEOARTHRITIS' reason for change: Data Entry Error | | 30 Oct 2020 16:36:20 |
| User opened query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid, Osteoarthritis, etc.) and the location. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. | | 26 Oct 2020 10:34:56 |
| ' (Site from DM). | | |
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Arthropathies NEC, PT: Arthritis, LLT: Arthritis - version MedDRA\\23.0. | Coder Import (b) (4) | 03 Sep 2020 21:40:45 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 03 Sep 2020 21:40:45 |
| Data point term sent to Coder | System | 03 Sep 2020 21:39:58 |
| User entered 'ARTHRITIS' | Crystal Rowell (b) (4) | 03 Sep 2020 21:39:23 |
| | (b) (4) | |

US3362244

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered 'UN UNK 2010' reason for change: | (b) (4) | |
| Data Entry Error | Crystal Rowell (b) (4) | 03 Sep 2020 21:39:35 |
| User entered 'UN UNK 2020' | (b) (4) | |
| | Crystal Rowell (b) (4) | 03 Sep 2020 21:39:23 |
| | (b) (4) | |

US3362244

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:14:58

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered '0' | Crystal Rowell (b) (4) | 03 Sep 2020 21:39:23 |

US3362244

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:14:58

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered 'Yes (Y)' | Crystal Rowell (b) (4) | 03 Sep 2020 21:39:23 |

US3362244

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered empty. | Crystal Rowell (b) (4) | 03 Sep 2020 21:39:23 |

US3362244

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:14:58

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered '0' | Crystal Rowell (b) (4) | 03 Sep 2020 21:39:23 |

US3362244

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User entered 'Jan 2010' | System | 03 Sep 2020 21:39:35 |
| User entered 'Jan 2020' | System | 03 Sep 2020 21:39:23 |

US3362244

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User entered '2010' | System | 03 Sep 2020 21:39:35 |
| User entered '2020' | System | 03 Sep 2020 21:39:23 |

US3362244

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User entered empty. | System | 03 Sep 2020 21:39:23 |

US3362244

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User entered empty. | System | 03 Sep 2020 21:39:23 |

US3362244

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:14:58

[Condition](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User coded data point as SOC: Social circumstances, HLT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0. | Coder Import (b) (4) | 17 Sep 2020 18:07:40 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 17 Sep 2020 18:07:40 |
| Data point term sent to Coder | System | 17 Sep 2020 18:06:52 |
| User entered 'post menopause' | (b) (4), (b) (6) | 17 Sep 2020 18:05:57 |

US3362244

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered empty. | (b) (4), (b) (6) | 17 Sep 2020 18:05:57 |

US3362244

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:14:58

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered 'I' | (b) (4), (b) (6) | 17 Sep 2020 18:05:57 |

US3362244

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:14:58

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 17 Sep 2020 18:05:57 |

US3362244

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered empty. | (b) (4), (b) (6) | 17 Sep 2020 18:05:57 |

US3362244

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:14:58

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered '0' | (b) (4), (b) (6) | 17 Sep 2020 18:05:57 |

US3362244

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User entered empty. | System | 17 Sep 2020 18:05:57 |

US3362244

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User entered empty. | System | 17 Sep 2020 18:05:57 |

US3362244

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User entered empty. | System | 17 Sep 2020 18:05:57 |

US3362244

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User entered empty. | System | 17 Sep 2020 18:05:57 |

US3362244

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:14:58

[Condition](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User coded data point as SOC: Congenital, familial and genetic disorders, HLGT: Blood and lymphatic system disorders congenital, HLT: Haemoglobinopathies congenital, PT: Thalassaemia alpha, LLT: Thalassaemia alpha - version MedDRA\\23.0. | Coder Import (b) (4) | 30 Oct 2020 19:31:56 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 30 Oct 2020 19:31:56 |
| Data point term sent to Coder | System | 30 Oct 2020 19:31:19 |
| User entered 'Alpha Thalassemia' | Crystal Rowell (b) (4) | 30 Oct 2020 19:30:19 |

US3362244

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered empty. | Crystal Rowell (b) (4) | 30 Oct 2020 19:30:19 |

US3362244

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:14:58

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered 'I' | Crystal Rowell (b) (4) | 30 Oct 2020 19:30:19 |

US3362244

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:14:58

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered 'Yes (Y)' | Crystal Rowell (b) (4) | 30 Oct 2020 19:30:19 |

US3362244

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered empty. | Crystal Rowell (b) (4) | 30 Oct 2020 19:30:19 |

US3362244

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:14:58

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered '0' | Crystal Rowell (b) (4) | 30 Oct 2020 19:30:19 |

US3362244

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User entered empty. | System | 30 Oct 2020 19:30:19 |

US3362244

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User entered empty. | System | 30 Oct 2020 19:30:19 |

US3362244

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User entered empty. | System | 30 Oct 2020 19:30:19 |

US3362244

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User entered empty. | System | 30 Oct 2020 19:30:19 |

US3362244

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:14:58

Condition

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Upper limb fracture, LLT: Elbow fracture - version MedDRA\\23.0. | Coder Import (b) (4) | 12 Nov 2020 21:11:34 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 12 Nov 2020 21:11:34 |
| Data point term sent to Coder | System | 12 Nov 2020 21:10:27 |
| User entered 'Fractured left elbow' | Crystal Rowell (b) (4) | 12 Nov 2020 21:09:43 |

US3362244

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered 'un Feb 2020' | Crystal Rowell (b) (4) | 12 Nov 2020 21:09:43 |

US3362244

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:14:58

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered '0' | Crystal Rowell (b) (4) | 12 Nov 2020 21:09:43 |

US3362244

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:14:58

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered 'No (N)' | Crystal Rowell (b) (4) | 12 Nov 2020 21:09:43 |

US3362244

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered 'un Feb 2020' | Crystal Rowell (b) (4) | 12 Nov 2020 21:09:43 |

US3362244

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:14:58

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered '0' | Crystal Rowell (b) (4) | 12 Nov 2020 21:09:43 |

US3362244

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User entered 'Feb 2020' | System | 12 Nov 2020 21:09:43 |

US3362244

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User entered '2020' | System | 12 Nov 2020 21:09:43 |

US3362244

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User entered 'Feb 2020' | System | 12 Nov 2020 21:09:43 |

US3362244

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User entered '2020' | System | 12 Nov 2020 21:09:43 |

US3362244

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:14:58

Condition

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Pain in hip - version MedDRA\\23.0. | Coder Import (b) (4) | 12 Nov 2020 21:15:34 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 12 Nov 2020 21:15:34 |
| Data point term sent to Coder | System | 12 Nov 2020 21:14:33 |
| User entered 'left hip pain' | Crystal Rowell (b) (4) | 12 Nov 2020 21:14:32 |

US3362244

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered 'un Feb 2020' | Crystal Rowell (b) (4) | 12 Nov 2020 21:14:32 |

US3362244

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:14:58

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered '0' | Crystal Rowell (b) (4) | 12 Nov 2020 21:14:32 |

US3362244

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:14:58

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered 'Yes (Y)' | Crystal Rowell (b) (4) | 12 Nov 2020 21:14:32 |

US3362244

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered empty. | Crystal Rowell (b) (4) | 12 Nov 2020 21:14:32 |

US3362244

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:14:58

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered '0' | Crystal Rowell (b) (4) | 12 Nov 2020 21:14:32 |

US3362244

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User entered 'Feb 2020' | System | 12 Nov 2020 21:14:32 |

US3362244

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User entered '2020' | System | 12 Nov 2020 21:14:32 |

US3362244

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User entered empty. | System | 12 Nov 2020 21:14:32 |

US3362244

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User entered empty. | System | 12 Nov 2020 21:14:32 |

US3362244

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:14:58

Condition

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Intervertebral disc disorders NEC, PT: Intervertebral disc degeneration, LLT: Degenerative disc disease - version MedDRA\\23.0. | Coder Import (b) (4) | 12 Nov 2020 21:31:34 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 12 Nov 2020 21:31:34 |
| Data point term sent to Coder | System | 12 Nov 2020 21:15:34 |
| User entered 'degenerative disc disease' | Crystal Rowell (b) (4) | 12 Nov 2020 21:15:21 |

US3362244

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered '27 Apr 2020' | Crystal Rowell (b) (4) | 12 Nov 2020 21:15:21 |

US3362244

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:14:58

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered '0' | Crystal Rowell (b) (4) | 12 Nov 2020 21:15:21 |

US3362244

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:14:58

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered 'Yes (Y)' | Crystal Rowell (b) (4) | 12 Nov 2020 21:15:21 |

US3362244

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered empty. | Crystal Rowell (b) (4) | 12 Nov 2020 21:15:21 |

US3362244

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:14:58

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered '0' | Crystal Rowell (b) (4) | 12 Nov 2020 21:15:21 |

US3362244

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User entered 'Apr 2020' | System | 12 Nov 2020 21:15:21 |

US3362244

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User entered '2020' | System | 12 Nov 2020 21:15:21 |

US3362244

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User entered empty. | System | 12 Nov 2020 21:15:21 |

US3362244

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User entered empty. | System | 12 Nov 2020 21:15:21 |

US3362244

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:14:58

[Condition](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User coded data point as SOC: Cardiac disorders, HLT: Cardiac arrhythmias, HLT: Rate and rhythm disorders NEC, PT: Arrhythmia, LLT: Arrhythmia - version MedDRA\\23.0. | Coder Import (b) (4) | 12 Nov 2020 23:39:44 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) | 12 Nov 2020 23:39:44 |
| Data point term sent to Coder | System | 12 Nov 2020 21:16:35 |
| User entered 'abnormal heart rhythm' | Crystal Rowell (b) (4) | 12 Nov 2020 21:15:50 |

US3362244

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered empty. | Crystal Rowell (b) (4) | 12 Nov 2020 21:15:50 |

US3362244

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:14:58

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered 'I' | Crystal Rowell (b) (4) | 12 Nov 2020 21:15:50 |

US3362244

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:14:58

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered 'Yes (Y)' | Crystal Rowell (b) (4) | 12 Nov 2020 21:15:50 |

US3362244

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered empty. | Crystal Rowell (b) (4) | 12 Nov 2020 21:15:50 |

US3362244

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:14:58

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered '0' | Crystal Rowell (b) (4) | 12 Nov 2020 21:15:50 |

US3362244

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User entered empty. | System | 12 Nov 2020 21:15:50 |

US3362244

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User entered empty. | System | 12 Nov 2020 21:15:50 |

US3362244

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User entered empty. | System | 12 Nov 2020 21:15:50 |

US3362244

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User entered empty. | System | 12 Nov 2020 21:15:50 |

US3362244

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:58

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 25 Aug 2020 14:57:22 |

US3362244

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:58

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered '24 Aug 2020' | (b) (4), (b) (6) | 25 Aug 2020 14:57:22 |

US3362244

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered '13:54' | (b) (4), (b) (6) | 25 Aug 2020 14:57:22 |

US3362244

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User entered '24 Aug 2020 13:54' | System | 25 Aug 2020 14:57:22 |

US3362244

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered '164.2' cm | (b) (4), (b) (6) | 25 Aug 2020 14:57:22 |
| DataPoint set to visible. | System | 24 Aug 2020 20:14:41 |

US3362244

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered '55.7' kg | (b) (4) (b) (4), (b) (6) | 25 Aug 2020 14:57:22 |
| DataPoint set to visible. | System | 24 Aug 2020 20:14:41 |

US3362244

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:58

BMI (xxx.x)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| Amendment Manager: User entered '20.65898' | System | 17 Sep 2020 00:21:42 |
| User entered '20.7' | System | 25 Aug 2020 14:57:22 |
| DataPoint set to visible. | System | 24 Aug 2020 20:14:41 |

US3362244

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:58

[BMI units](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User entered 'kg/m2' | System | 25 Aug 2020 14:57:22 |
| DataPoint set to visible. | System | 24 Aug 2020 20:14:41 |

US3362244

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:58

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User closed query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. For Visit 1 Day 1 Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 23 Sep 2020 07:32:52 |
| Query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. For Visit 1 Day 1 Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly.' answered with 'Data updated per query resolution.' (Site from DM). | (b) (4), (b) (6) | 22 Sep 2020 14:58:18 |
| User entered missing code ND - Not Done; reason for change Per Query Resolution | (b) (4), (b) (6) | 22 Sep 2020 14:58:11 |
| User opened query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. For Visit 1 Day 1 Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly.' (Site from DM). | (b) (4), (b) (6) | 22 Sep 2020 13:50:40 |
| User entered '36.6' C | (b) (4), (b) (6) | 25 Aug 2020 14:57:22 |

US3362244

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:58

[Route of measurement](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered empty; reason for change Per Query Resolution | (b) (4), (b) (6) | 22 Sep 2020 14:58:11 |
| User entered 'Oral (Oral)' | (b) (4), (b) (6) | 25 Aug 2020 14:57:22 |

US3362244

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:58

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered empty. | (b) (4), (b) (6) | 25 Aug 2020 14:57:22 |

US3362244

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:58

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered missing code ND - Not Done; reason for change Per Query Resolution | (b) (4), (b) (6) | 22 Sep 2020 14:58:11 |
| User entered '70' | (b) (4), (b) (6) | 25 Aug 2020 14:57:22 |

US3362244

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:58

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User entered 'bpm' | System | 25 Aug 2020 14:57:22 |

US3362244

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered missing code ND - Not Done; reason for change Per Query Resolution | (b) (4), (b) (6) | 22 Sep 2020 14:58:11 |
| User entered '18' | (b) (4), (b) (6) | 25 Aug 2020 14:57:22 |

US3362244

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:58

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User entered 'breaths/min' | System | 25 Aug 2020 14:57:22 |

US3362244

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered missing code ND - Not Done; reason for change Per Query Resolution | (b) (4), (b) (6) | 22 Sep 2020 14:58:11 |
| User entered '158' | (b) (4), (b) (6) | 25 Aug 2020 14:57:22 |

US3362244

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:58

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User entered 'mmHg' | System | 25 Aug 2020 14:57:22 |

US3362244

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:58

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered missing code ND - Not Done; reason for change Per Query Resolution | (b) (4), (b) (6) | 22 Sep 2020 14:58:11 |
| User entered '95' | (b) (4), (b) (6) | 25 Aug 2020 14:57:22 |

US3362244

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:58

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User entered 'mmHg' | System | 25 Aug 2020 14:57:22 |

US3362244

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:58

[Height \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| | | |

US3362244

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:58

[Weight \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| | | |

US3362244

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:14:58

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 25 Aug 2020 14:57:45 |

US3362244

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:14:58

Date of examination (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered '24 Aug 2020' | (b) (4), (b) (6) | 25 Aug 2020 14:57:45 |

US3362244

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:14:58

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered '24 Aug 2020' | (b) (4), (b) (6) | 25 Aug 2020 15:03:46 |

US3362244

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered 'No (N)' | (b) (4), (b) (6) | 25 Aug 2020 15:03:46 |

US3362244

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:14:58

If No, what is the reason?

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User closed query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 22 Sep 2020 06:32:48 |
| Query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate.' answered with 'post menopause is entered in ecrf' (Site from DM). | (b) (4), (b) (6) | 17 Sep 2020 18:06:12 |
| User opened query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate.' (Site from DM). | (b) (4), (b) (6) | 17 Sep 2020 09:18:44 |
| User entered 'Post-menopausal (POST-MENOPAUSAL)' | (b) (4), (b) (6) | 25 Aug 2020 15:03:46 |

US3362244

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:14:58

If Partner medically sterile or Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered empty. | (b) (4), (b) (6) | 25 Aug 2020 15:03:46 |

US3362244

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered empty. | (b) (4), (b) (6) | 25 Aug 2020 15:03:46 |

US3362244

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:14:58

[Date of surgery unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered '0' | (b) (4), (b) (6) | 25 Aug 2020 15:03:46 |

US3362244

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered empty. | (b) (4), (b) (6) | 25 Aug 2020 15:03:46 |

US3362244

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:14:58

[Date of last menstruation unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered 'I' | (b) (4), (b) (6) | 25 Aug 2020 15:03:46 |

US3362244

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:14:58

[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 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 25 Aug 2020 15:04:34 |

US3362244

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:14:58

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 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered 'No (N)' | (b) (4), (b) (6) | 25 Aug 2020 15:04:34 |

US3362244

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:14:58

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 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered 'No (N)' | (b) (4), (b) (6) | 25 Aug 2020 15:04:34 |

US3362244

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:14:58

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 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered 'No (N)' | (b) (4), (b) (6) | 25 Aug 2020 15:04:34 |

US3362244

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:14:58

[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 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered 'No (N)' | (b) (4), (b) (6) | 25 Aug 2020 15:04:34 |

US3362244

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:14:58

[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 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered 'No (N)' | (b) (4), (b) (6) | 25 Aug 2020 15:04:34 |

US3362244

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:14:58

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 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered 'No (N)' | (b) (4), (b) (6) | 25 Aug 2020 15:04:34 |

US3362244

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:14:58

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 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered 'No (N)' | (b) (4), (b) (6) | 25 Aug 2020 15:04:34 |

US3362244

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:14:58

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 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 25 Aug 2020 15:04:34 |

US3362244

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:14:58

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 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered 'No (N)' | (b) (4), (b) (6) | 25 Aug 2020 15:04:34 |

US3362244

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:14:58

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 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered 'No (N)' | (b) (4), (b) (6) | 25 Aug 2020 15:04:34 |

US3362244

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:14:58

Other

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered 'No (N)' | (b) (4), (b) (6) | 25 Aug 2020 15:04:34 |

US3362244

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:14:58

[Specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered empty. | (b) (4), (b) (6) | 25 Aug 2020 15:04:34 |

US3362244

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:14:58

No Risk Identified

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered '0' | (b) (4), (b) (6) | 25 Aug 2020 15:04:34 |

US3362244

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered '0' | (b) (4), (b) (6) | 25 Aug 2020 15:04:34 |

US3362244

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:14:58

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 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered '0' | (b) (4), (b) (6) | 25 Aug 2020 15:04:34 |

US3362244

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:14:58

[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 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered '0' | (b) (4), (b) (6) | 25 Aug 2020 15:04:34 |

US3362244

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:14:58

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 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered '0' | (b) (4), (b) (6) | 25 Aug 2020 15:04:34 |

US3362244

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered '0' | (b) (4), (b) (6) | 25 Aug 2020 15:04:34 |

US3362244

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:14:58

Other

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered 'I' | (b) (4), (b) (6) | 25 Aug 2020 15:04:34 |

US3362244

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:14:58

[Specify](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 21:24:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 10 Apr 2021 00:36:58 |
| User entered 'Lives in a bed and breakfast (b) (6) | (b) (4), (b) (6) | 25 Aug 2020 15:04:34 |

US3362244

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:14:58

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 25 Aug 2020 15:04:50 |

US3362244

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered '24 Aug 2020' | (b) (4), (b) (6) | 25 Aug 2020 15:04:50 |

US3362244

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered 'Clinic (Clinic)' | (b) (4) (b) (4), (b) (6) | 25 Aug 2020 15:04:50 |

US3362244

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:14:58

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User entered 'VISIT1' | System | 25 Aug 2020 15:04:50 |

US3362244

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered '24 AUG 2020' | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 24 Aug 2020 19:40:17 |

US3362244

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered '187957' | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 24 Aug 2020 19:40:17 |

US3362244

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|-------------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered '>=65 years (3)' | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 24 Aug 2020 19:40:17 |

US3362244

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:14:58

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) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered 'No (N)' | (b) (4), (b) (6) | 25 Aug 2020 15:05:09 |

US3362244

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:14:58

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) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered 'No (N)' | (b) (4), (b) (6) | 25 Aug 2020 15:05:09 |

US3362244

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered 'No (N)' | (b) (4), (b) (6) | 25 Aug 2020 15:05:09 |

US3362244

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:14:58

[Diabetes \(Type I, Type 2, or gestational\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered 'No (N)' | (b) (4), (b) (6) | 25 Aug 2020 15:05:09 |

US3362244

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:14:58

[Liver Disease](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered 'No (N)' | (b) (4), (b) (6) | 25 Aug 2020 15:05:09 |

US3362244

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:14:58

[Human Immunodeficiency Virus \(HIV\) infection](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered 'No (N)' | Amy Thomassie (b) (4) | 24 Sep 2020 00:12:50 |
| Amendment Manager: DataPoint set to visible. | System | 19 Sep 2020 10:40:19 |
| Amendment Manager inserted this DataPoint. | System | 19 Sep 2020 02:43:10 |

US3362244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:14:58

Height

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User closed query 'Per CDM: According to CCGs page 15 to 16 -"If a participant is screened, enrolled, randomized, and dosed on the same day", Height and Weight should be recorded as ND under Visit 1 Day 1 Folder section of the eCRF. Please update as needed. ' (Site from DM). | (b) (4) (b) (4), (b) (6) | 24 Sep 2020 05:21:02 |
| Query 'Per CDM: According to CCGs page 15 to 16 -"If a participant is screened, enrolled, randomized, and dosed on the same day", Height and Weight should be recorded as ND under Visit 1 Day 1 Folder section of the eCRF. Please update as needed. ' answered with 'UPDATED' (Site from DM). | (b) (4), (b) (6) | 23 Sep 2020 13:11:26 |
| User entered missing code ND - Not Done; reason for change Per Query Resolution | (b) (4), (b) (6) | 23 Sep 2020 13:11:22 |
| User opened query 'Per CDM: According to CCGs page 15 to 16 -"If a participant is screened, enrolled, randomized, and dosed on the same day", Height and Weight should be recorded as ND under Visit 1 Day 1 Folder section of the eCRF. Please update as needed. ' (Site from DM). | (b) (4), (b) (6) | 23 Sep 2020 07:33:24 |
| User entered '164.2' cm | (b) (4), (b) (6) | 25 Aug 2020 15:07:23 |

US3362244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:14:58

Weight

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered missing code ND - Not Done; reason for change Per Query Resolution | (b) (4), (b) (6) | 23 Sep 2020 13:11:22 |
| User entered '55.7' kg | (b) (4), (b) (6) | 25 Aug 2020 15:07:23 |

US3362244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:14:58

Height

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User closed query 'Per CDM: According to CCGs page 15 to 16 -"If a participant is screened, enrolled, randomized, and dosed on the same day", Height and Weight should be recorded as ND under Visit 1 Day 1 Folder section of the eCRF. Please update as needed. ' (Site from DM). | (b) (4) (b) (4), (b) (6) | 24 Sep 2020 05:21:02 |
| Query 'Per CDM: According to CCGs page 15 to 16 -"If a participant is screened, enrolled, randomized, and dosed on the same day", Height and Weight should be recorded as ND under Visit 1 Day 1 Folder section of the eCRF. Please update as needed. ' answered with 'UPDATED' (Site from DM). | (b) (4), (b) (6) | 23 Sep 2020 13:11:26 |
| User entered missing code ND - Not Done; reason for change Per Query Resolution | (b) (4), (b) (6) | 23 Sep 2020 13:11:22 |
| User opened query 'Per CDM: According to CCGs page 15 to 16 -"If a participant is screened, enrolled, randomized, and dosed on the same day", Height and Weight should be recorded as ND under Visit 1 Day 1 Folder section of the eCRF. Please update as needed. ' (Site from DM). | (b) (4), (b) (6) | 23 Sep 2020 07:33:24 |
| User entered '164.2' cm | (b) (4), (b) (6) | 25 Aug 2020 15:07:23 |

US3362244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:14:58

[Weight](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered missing code ND - Not Done; reason for change Per Query Resolution | (b) (4), (b) (6) | 23 Sep 2020 13:11:22 |
| User entered '55.7' kg | (b) (4), (b) (6) | 25 Aug 2020 15:07:23 |

US3362244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:58

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User accepted default value 'Pre-Dose (PREDOSE)' | (b) (4), (b) (6) | 25 Aug 2020 15:07:23 |

US3362244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:58

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 25 Aug 2020 15:07:23 |

US3362244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:58

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered '24 Aug 2020' | (b) (4) (b) (4), (b) (6) | 25 Aug 2020 15:07:23 |

US3362244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered '13:54' | (b) (4), (b) (6) | 25 Aug 2020 15:07:23 |

US3362244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User entered '24 Aug 2020 13:54' | System | 25 Aug 2020 15:07:23 |

US3362244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:58

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered '36.6' C | (b) (4), (b) (6) | 25 Aug 2020 15:07:23 |

US3362244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:58

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered 'Oral (Oral)' | (b) (4) (b) (4), (b) (6) | 25 Aug 2020 15:07:23 |

US3362244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:58

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered empty. | (b) (4), (b) (6) | 25 Aug 2020 15:07:23 |

US3362244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:58

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered '70' | (b) (4), (b) (6) | 25 Aug 2020 15:07:23 |

US3362244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:58

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User entered 'bpm' | System | 25 Aug 2020 15:07:23 |

US3362244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered '18' | (b) (4) (b) (4), (b) (6) | 25 Aug 2020 15:07:23 |

US3362244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:58

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User entered 'breaths/min' | System | 25 Aug 2020 15:07:23 |

US3362244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:58

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System). | (b) (4) (b) (4), (b) (6) | 31 Aug 2020 20:47:13 |
| Query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS; runs normal at home and at last check up' (Site from System). | (b) (4), (b) (6) | 25 Aug 2020 15:09:34 |
| User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System). | System | 25 Aug 2020 15:07:23 |
| User entered '158' | (b) (4), (b) (6) | 25 Aug 2020 15:07:23 |

US3362244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:58

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User entered 'mmHg' | System | 25 Aug 2020 15:07:23 |

US3362244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:58

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered '95' | (b) (4), (b) (6) | 25 Aug 2020 15:07:23 |

US3362244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:58

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User entered 'mmHg' | System | 25 Aug 2020 15:07:23 |

US3362244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:14:58

Height

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User closed query 'Per CDM: According to CCGs page 15 to 16 -"If a participant is screened, enrolled, randomized, and dosed on the same day", Height and Weight should be recorded as ND under Visit 1 Day 1 Folder section of the eCRF. Please update as needed. ' (Site from DM). | (b) (4) (b) (4), (b) (6) | 24 Sep 2020 05:21:02 |
| Query 'Per CDM: According to CCGs page 15 to 16 -"If a participant is screened, enrolled, randomized, and dosed on the same day", Height and Weight should be recorded as ND under Visit 1 Day 1 Folder section of the eCRF. Please update as needed. ' answered with 'UPDATED' (Site from DM). | (b) (4), (b) (6) | 23 Sep 2020 13:11:26 |
| User entered missing code ND - Not Done; reason for change Per Query Resolution | (b) (4), (b) (6) | 23 Sep 2020 13:11:22 |
| User opened query 'Per CDM: According to CCGs page 15 to 16 -"If a participant is screened, enrolled, randomized, and dosed on the same day", Height and Weight should be recorded as ND under Visit 1 Day 1 Folder section of the eCRF. Please update as needed. ' (Site from DM). | (b) (4), (b) (6) | 23 Sep 2020 07:33:24 |
| User entered '164.2' cm | (b) (4), (b) (6) | 25 Aug 2020 15:07:23 |

US3362244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:14:58

[Weight](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered missing code ND - Not Done; reason for change Per Query Resolution | (b) (4), (b) (6) | 23 Sep 2020 13:11:22 |
| User entered '55.7' kg | (b) (4), (b) (6) | 25 Aug 2020 15:07:23 |

US3362244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:58

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User accepted default value 'Post-Dose (POSTDOSE)' | (b) (4), (b) (6) | 25 Aug 2020 15:07:23 |

US3362244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:58

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 25 Aug 2020 15:07:23 |

US3362244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:58

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered '24 Aug 2020' | (b) (4) (b) (4), (b) (6) | 25 Aug 2020 15:07:23 |

US3362244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered '15:37' | (b) (4), (b) (6) | 25 Aug 2020 15:07:23 |

US3362244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User entered '24 Aug 2020 15:37' | System | 25 Aug 2020 15:07:23 |

US3362244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:58

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered '36.8' C | (b) (4), (b) (6) | 25 Aug 2020 15:07:23 |

US3362244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:58

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered 'Oral (Oral)' | (b) (4) (b) (4), (b) (6) | 25 Aug 2020 15:07:23 |

US3362244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:58

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered empty. | (b) (4), (b) (6) | 25 Aug 2020 15:07:23 |

US3362244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:58

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered '62' | (b) (4), (b) (6) | 25 Aug 2020 15:07:23 |

US3362244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:58

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User entered 'bpm' | System | 25 Aug 2020 15:07:23 |

US3362244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered '18' | (b) (4), (b) (6) | 25 Aug 2020 15:07:23 |

US3362244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:58

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User entered 'breaths/min' | System | 25 Aug 2020 15:07:23 |

US3362244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:58

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered '130' | (b) (4), (b) (6) | 25 Aug 2020 15:07:23 |

US3362244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:58

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User entered 'mmHg' | System | 25 Aug 2020 15:07:23 |

US3362244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered '81' | (b) (4), (b) (6) | 25 Aug 2020 15:07:23 |

US3362244

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:58

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User entered 'mmHg' | System | 25 Aug 2020 15:07:23 |

US3362244

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:14:58

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 25 Aug 2020 15:09:59 |

US3362244

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:14:58

Date of examination (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered '24 Aug 2020' | (b) (4), (b) (6) | 25 Aug 2020 15:09:59 |

US3362244

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:14:58

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 24 Aug 2020 20:15:12 |

US3362244

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:14:58

[If No, reason not given](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 24 Aug 2020 20:15:12 |

US3362244

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered empty. | (b) (4), (b) (6) | 24 Aug 2020 20:15:12 |

US3362244

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:14:58

[What was the study treatment?](#)

| Audit | User | Time (GMT) |
|-------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User entered 'MRNA-1273 OR PLACEBO' | System | 24 Aug 2020 20:15:12 |

US3362244

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:14:58

What was the treatment date? (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered '24 Aug 2020' | (b) (4) (b) (4), (b) (6) | 24 Aug 2020 20:15:12 |

US3362244

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered '14:58' | (b) (4) (b) (4), (b) (6) | 24 Aug 2020 20:15:12 |

US3362244

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User entered '24 Aug 2020 14:58' | System | 24 Aug 2020 20:15:12 |

US3362244

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|------------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered 'Left Arm (LEFT ARM)' | (b) (4) (b) (4), (b) (6) | 24 Aug 2020 20:15:12 |

US3362244

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User entered 'ONCE' | System | 24 Aug 2020 20:15:12 |

US3362244

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:14:58

What was the route of administration for the study treatment?

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User entered 'INTRAMUSCULAR' | System | 24 Aug 2020 20:15:12 |

US3362244

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:14:58

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 25 Aug 2020 15:10:37 |

US3362244

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:14:58

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered '24 Aug 2020' | (b) (4), (b) (6) | 25 Aug 2020 15:10:37 |

US3362244

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:14:58

[Collection time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered '14:32' | (b) (4), (b) (6) | 25 Aug 2020 15:10:37 |

US3362244

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User entered '24 Aug 2020 14:32' | System | 25 Aug 2020 15:10:37 |

US3362244

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:14:58

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered '24 Aug 2020' | (b) (4) (b) (4), (b) (6) | 25 Aug 2020 15:11:02 |

US3362244

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:14:58

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | (b) (4), (b) (6) | 25 Aug 2020 15:11:02 |

US3362244

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:14:58

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 25 Aug 2020 15:11:02 |

US3362244

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:14:58

[Collection time \(00:00 - 23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered '14:12' | (b) (4), (b) (6) | 25 Aug 2020 15:11:02 |

US3362244

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User entered '24 Aug 2020 14:12' | System | 25 Aug 2020 15:11:02 |

US3362244

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:14:58

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | (b) (4), (b) (6) | 25 Aug 2020 15:11:02 |

US3362244

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:14:58

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered 'No (N)' | (b) (4), (b) (6) | 25 Aug 2020 15:11:02 |

US3362244

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:14:58

[Collection time \(00:00 - 23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered empty. | (b) (4), (b) (6) | 25 Aug 2020 15:11:02 |

US3362244

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User entered empty. | System | 25 Aug 2020 15:11:02 |

US3362244

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:14:58

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 25 Aug 2020 15:13:55 |

US3362244

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:14:58

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User entered 'I' | System | 25 Aug 2020 15:13:55 |

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| Data entry locked. | System | 24 Aug 2020 20:15:12 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 24 Aug 2020 20:15:12 |

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:14:58

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-24T15:32:03', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'af9118eb-1a39-4274-a7fc-4121a3a73e96' | System | 24 Aug 2020 20:32:42 |
| User entered 'Yes (Y)' | System | 24 Aug 2020 20:32:42 |

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:14:58

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-24T15:32:14', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'af9118eb-1a39-4274-a7fc-4121a3a73e96' | System | 24 Aug 2020 20:32:42 |
| User entered '98.3' | System | 24 Aug 2020 20:32:42 |

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-24T15:32:26', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'af9118eb-1a39-4274-a7fc-4121a3a73e96' | System | 24 Aug 2020 20:32:42 |
| User entered 'No (N)' | System | 24 Aug 2020 20:32:42 |

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:14:58

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-24T15:32:36', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'af9118eb-1a39-4274-a7fc-4121a3a73e96' | System | 24 Aug 2020 20:32:42 |
| User entered '24 Aug 2020 15:32' | System | 24 Aug 2020 20:32:42 |

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:14:58

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| User entered '24 Aug 2020 15:18' | System | 24 Aug 2020 20:15:12 |

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:14:58

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| User entered '24 Aug 2020 17:48' | System | 24 Aug 2020 20:15:12 |

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| Data entry locked. | System | 24 Aug 2020 20:15:12 |
| User entered 'Day 1, after vaccination (at home)' | System | 24 Aug 2020 20:15:12 |

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:14:58

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-24T20:24:41', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '2b041188-345a-4672-af37-19e64258b737' | System | 25 Aug 2020 01:25:14 |
| User entered 'Yes (Y)' | System | 25 Aug 2020 01:25:14 |

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:14:58

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-24T20:24:52', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '2b041188-345a-4672-af37-19e64258b737' | System | 25 Aug 2020 01:25:14 |
| User entered '97.3' | System | 25 Aug 2020 01:25:14 |

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-24T20:24:59', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '2b041188-345a-4672-af37-19e64258b737' | System | 25 Aug 2020 01:25:14 |
| User entered 'No (N)' | System | 25 Aug 2020 01:25:14 |

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:14:58

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-24T20:25:09', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '2b041188-345a-4672-af37-19e64258b737' | System | 25 Aug 2020 01:25:14 |
| User entered '24 Aug 2020 20:25' | System | 25 Aug 2020 01:25:14 |

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:14:58

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| User entered '24 Aug 2020 18:43' | System | 24 Aug 2020 20:15:12 |

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:14:58

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| User entered '25 Aug 2020 11:59' | System | 24 Aug 2020 20:15:12 |

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| Data entry locked. | System | 24 Aug 2020 20:15:12 |
| User entered 'Day 2' | System | 24 Aug 2020 20:15:12 |

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:14:58

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-25T12:36:40', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'ae723385-7d29-4c4f-aa8c-8e17f95b0d35' | System | 25 Aug 2020 17:37:15 |
| User entered 'Yes (Y)' | System | 25 Aug 2020 17:37:15 |

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:14:58

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-25T12:36:46', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'ae723385-7d29-4c4f-aa8c-8e17f95b0d35' | System | 25 Aug 2020 17:37:15 |
| User entered '97.3' | System | 25 Aug 2020 17:37:15 |

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-25T12:36:51', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'ae723385-7d29-4c4f-aa8c-8e17f95b0d35' | System | 25 Aug 2020 17:37:15 |
| User entered 'Yes (Y)' | System | 25 Aug 2020 17:37:15 |

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-25T12:37:02', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'ae723385-7d29-4c4f-aa8c-8e17f95b0d35' | System | 25 Aug 2020 17:37:15 |
| User entered '0' | System | 25 Aug 2020 17:37:15 |

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:14:58

To **PREVENT** pain or fever from occurring

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'con med list updated ' (Site from System). | (b) (4), (b) (6) | 07 Sep 2020 10:50:16 |
| User opened query 'Per the participant response, medication was taken to prevent 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). | Crystal Rowell (b) (4) | 31 Aug 2020 23:47:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-25T12:37:02', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'ae723385-7d29-4c4f-aa8c-8e17f95b0d35' | (b) (4) | |
| User entered '1' | System | 25 Aug 2020 17:37:15 |
| | System | 25 Aug 2020 17:37:15 |
| | System | 25 Aug 2020 17:37:15 |

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:14:58

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-25T12:37:10', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'ae723385-7d29-4c4f-aa8c-8e17f95b0d35' | System | 25 Aug 2020 17:37:15 |
| User entered '25 Aug 2020 12:37' | System | 25 Aug 2020 17:37:15 |

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:14:58

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| User entered '25 Aug 2020 12:00' | System | 24 Aug 2020 20:15:12 |

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:14:58

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| User entered '26 Aug 2020 11:59' | System | 24 Aug 2020 20:15:12 |

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| Data entry locked. | System | 24 Aug 2020 20:15:12 |
| User entered 'Day 3' | System | 24 Aug 2020 20:15:12 |

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:14:58

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-26T13:17:05', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '2f2ee995-d331-4167-ac90-dc23ea577fd0' | System | 26 Aug 2020 18:17:47 |
| User entered 'Yes (Y)' | System | 26 Aug 2020 18:17:47 |

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:14:58

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-26T13:17:19', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '2f2ee995-d331-4167-ac90-dc23ea577fd0' | System | 26 Aug 2020 18:17:47 |
| User entered '96.7' | System | 26 Aug 2020 18:17:47 |

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-26T13:17:23', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '2f2ee995-d331-4167-ac90-dc23ea577fd0' | System | 26 Aug 2020 18:17:47 |
| User entered 'Yes (Y)' | System | 26 Aug 2020 18:17:47 |

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-26T13:17:30', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '2f2ee995-d331-4167-ac90-dc23ea577fd0' | System | 26 Aug 2020 18:17:47 |
| User entered '0' | System | 26 Aug 2020 18:17:47 |

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:14:58

To **PREVENT** pain or fever from occurring

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'Participant was contacted. Subject took Tylenol Extra Strength 325mg for arthritis. Con med log will be updated' (Site from System). | (b) (4), (b) (6) | 15 Sep 2020 06:17:00 |
| User opened query 'Per the participant response, medication was taken to prevent 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). | (b) (4), (b) (6) | 14 Sep 2020 17:05:14 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-26T13:17:30', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '2f2ee995-d331-4167-ac90-dc23ea577fd0' | System | 26 Aug 2020 18:17:47 |
| User entered '1' | System | 26 Aug 2020 18:17:47 |

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:14:58

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-26T13:17:44', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '2f2ee995-d331-4167-ac90-dc23ea577fd0' | System | 26 Aug 2020 18:17:47 |
| User entered '26 Aug 2020 13:17' | System | 26 Aug 2020 18:17:47 |

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:14:58

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| User entered '26 Aug 2020 12:00' | System | 24 Aug 2020 20:15:12 |

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:14:58

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| User entered '27 Aug 2020 11:59' | System | 24 Aug 2020 20:15:12 |

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| Data entry locked. | System | 24 Aug 2020 20:15:12 |
| User entered 'Day 4' | System | 24 Aug 2020 20:15:12 |

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:14:58

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-27T12:27:09', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '8e918026-3fbb-43db-862e-8e2869476e02' | System | 27 Aug 2020 17:27:37 |
| User entered 'Yes (Y)' | System | 27 Aug 2020 17:27:37 |

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:14:58

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-27T12:27:18', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '8e918026-3fbb-43db-862e-8e2869476e02' | System | 27 Aug 2020 17:27:37 |
| User entered '97.3' | System | 27 Aug 2020 17:27:37 |

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-27T12:27:23', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '8e918026-3fbb-43db-862e-8e2869476e02' | System | 27 Aug 2020 17:27:37 |
| User entered 'Yes (Y)' | System | 27 Aug 2020 17:27:37 |

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-27T12:27:26', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '8e918026-3fbb-43db-862e-8e2869476e02' | System | 27 Aug 2020 17:27:37 |
| User entered '0' | System | 27 Aug 2020 17:27:37 |

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:14:58

To PREVENT pain or fever from occurring

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'Participant was contacted. Subject took Tylenol Extra Strength 325mg for arthritis. Con med log will be updated' (Site from System). | (b) (4), (b) (6) | 15 Sep 2020 06:16:56 |
| User opened query 'Per the participant response, medication was taken to prevent 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). | (b) (4), (b) (6) | 14 Sep 2020 17:05:23 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-27T12:27:26', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '8e918026-3fbb-43db-862e-8e2869476e02' | System | 27 Aug 2020 17:27:37 |
| User entered '1' | System | 27 Aug 2020 17:27:37 |

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:14:58

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-27T12:27:34', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '8e918026-3fbb-43db-862e-8e2869476e02' | System | 27 Aug 2020 17:27:37 |
| User entered '27 Aug 2020 12:27' | System | 27 Aug 2020 17:27:37 |

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:14:58

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| User entered '27 Aug 2020 12:00' | System | 24 Aug 2020 20:15:12 |

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:14:58

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| User entered '28 Aug 2020 11:59' | System | 24 Aug 2020 20:15:12 |

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| Data entry locked. | System | 24 Aug 2020 20:15:12 |
| User entered 'Day 5' | System | 24 Aug 2020 20:15:12 |

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:14:58

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-28T12:09:22', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'cc1a01bc-7a22-414c-9432-1552900724b9' | System | 28 Aug 2020 17:09:48 |
| User entered 'Yes (Y)' | System | 28 Aug 2020 17:09:48 |

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:14:58

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-28T12:09:29', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'cc1a01bc-7a22-414c-9432-1552900724b9' User entered '96.4' | System | 28 Aug 2020 17:09:48 |
| | System | 28 Aug 2020 17:09:48 |

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-28T12:09:33', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'cc1a01bc-7a22-414c-9432-1552900724b9' | System | 28 Aug 2020 17:09:48 |
| User entered 'No (N)' | System | 28 Aug 2020 17:09:48 |

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:14:58

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-28T12:09:41', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'cc1a01bc-7a22-414c-9432-1552900724b9' | System | 28 Aug 2020 17:09:48 |
| User entered '28 Aug 2020 12:09' | System | 28 Aug 2020 17:09:48 |

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:14:58

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| User entered '28 Aug 2020 12:00' | System | 24 Aug 2020 20:15:12 |

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:14:58

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| User entered '29 Aug 2020 11:59' | System | 24 Aug 2020 20:15:12 |

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| Data entry locked. | System | 24 Aug 2020 20:15:12 |
| User entered 'Day 6' | System | 24 Aug 2020 20:15:12 |

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:14:58

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-29T12:16:55', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'c3f62e15-855c-46fc-a04b-4c8cb896b0d7' | System | 29 Aug 2020 17:17:26 |
| User entered 'Yes (Y)' | System | 29 Aug 2020 17:17:26 |

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:14:58

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-29T12:17:07', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'c3f62e15-855c-46fc-a04b-4c8cb896b0d7' | System | 29 Aug 2020 17:17:26 |
| User entered '97.7' | System | 29 Aug 2020 17:17:26 |

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-29T12:17:18', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'c3f62e15-855c-46fc-a04b-4c8cb896b0d7' | System | 29 Aug 2020 17:17:26 |
| User entered 'No (N)' | System | 29 Aug 2020 17:17:26 |

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:14:58

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-29T12:17:23', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'c3f62e15-855c-46fc-a04b-4c8cb896b0d7' | System | 29 Aug 2020 17:17:26 |
| User entered '29 Aug 2020 12:17' | System | 29 Aug 2020 17:17:26 |

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:14:58

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| User entered '29 Aug 2020 12:00' | System | 24 Aug 2020 20:15:12 |

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:14:58

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| User entered '30 Aug 2020 11:59' | System | 24 Aug 2020 20:15:12 |

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| Data entry locked. | System | 24 Aug 2020 20:15:12 |
| User entered 'Day 7' | System | 24 Aug 2020 20:15:12 |

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:14:58

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-30T12:23:15', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '88bac18d-2495-4b6d-85b6-d51c611aa234' | System | 30 Aug 2020 17:23:42 |
| User entered 'Yes (Y)' | System | 30 Aug 2020 17:23:42 |

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:14:58

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-30T12:23:26', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '88bac18d-2495-4b6d-85b6-d51c611aa234' | System | 30 Aug 2020 17:23:42 |
| User entered '96.8' | System | 30 Aug 2020 17:23:42 |

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-30T12:23:31', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '88bac18d-2495-4b6d-85b6-d51c611aa234' | System | 30 Aug 2020 17:23:42 |
| User entered 'No (N)' | System | 30 Aug 2020 17:23:42 |

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:14:58

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-30T12:23:37', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '88bac18d-2495-4b6d-85b6-d51c611aa234' | System | 30 Aug 2020 17:23:42 |
| User entered '30 Aug 2020 12:23' | System | 30 Aug 2020 17:23:42 |

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:14:58

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| User entered '30 Aug 2020 12:00' | System | 24 Aug 2020 20:15:12 |

US3362244

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:14:58

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| User entered '31 Aug 2020 11:59' | System | 24 Aug 2020 20:15:12 |

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| Data entry locked. | System | 24 Aug 2020 20:15:12 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 24 Aug 2020 20:15:12 |

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:14:58

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-24T15:33:04', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '07c4e584-095f-4af3-ba05-e3567c2144cc' | System | 24 Aug 2020 20:33:49 |
| User entered 'None (1)' | System | 24 Aug 2020 20:33:49 |

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-24T15:33:09', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '07c4e584-095f-4af3-ba05-e3567c2144cc' | System | 24 Aug 2020 20:33:49 |
| User entered 'No (N)' | System | 24 Aug 2020 20:33:49 |

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-24T15:33:14', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '07c4e584-095f-4af3-ba05-e3567c2144cc' | System | 24 Aug 2020 20:33:49 |
| User entered 'No (N)' | System | 24 Aug 2020 20:33:49 |

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:14:58

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-24T15:33:28', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '07c4e584-095f-4af3-ba05-e3567c2144cc' | System | 24 Aug 2020 20:33:49 |
| User entered 'None (1)' | System | 24 Aug 2020 20:33:49 |

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:14:58

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-24T15:33:45', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '07c4e584-095f-4af3-ba05-e3567c2144cc' | System | 24 Aug 2020 20:33:49 |
| User entered '24 Aug 2020 15:33' | System | 24 Aug 2020 20:33:49 |

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:14:58

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| User entered '24 Aug 2020 15:18' | System | 24 Aug 2020 20:15:12 |

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:14:58

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| User entered '24 Aug 2020 17:48' | System | 24 Aug 2020 20:15:12 |

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| Data entry locked. | System | 24 Aug 2020 20:15:12 |
| User entered 'Day 1, after vaccination (at home)' | System | 24 Aug 2020 20:15:12 |

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:14:58

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-24T20:26:06', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '1375d2d8-e97e-4ce2-9985-105b615d02fe' | System | 25 Aug 2020 01:26:36 |
| User entered 'None (1)' | System | 25 Aug 2020 01:26:36 |

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:14:58

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-24T20:26:10', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '1375d2d8-e97e-4ce2-9985-105b615d02fe' | System | 25 Aug 2020 01:26:36 |
| User entered 'No (N)' | System | 25 Aug 2020 01:26:36 |

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-24T20:26:14', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '1375d2d8-e97e-4ce2-9985-105b615d02fe' | System | 25 Aug 2020 01:26:36 |
| User entered 'No (N)' | System | 25 Aug 2020 01:26:36 |

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:14:58

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-24T20:26:22', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '1375d2d8-e97e-4ce2-9985-105b615d02fe' | System | 25 Aug 2020 01:26:36 |
| User entered 'None (1)' | System | 25 Aug 2020 01:26:36 |

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:14:58

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-24T20:26:32', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '1375d2d8-e97e-4ce2-9985-105b615d02fe' | System | 25 Aug 2020 01:26:36 |
| User entered '24 Aug 2020 20:26' | System | 25 Aug 2020 01:26:36 |

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:14:58

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| User entered '24 Aug 2020 18:43' | System | 24 Aug 2020 20:15:12 |

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:14:58

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| User entered '25 Aug 2020 11:59' | System | 24 Aug 2020 20:15:12 |

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| Data entry locked. | System | 24 Aug 2020 20:15:12 |
| User entered 'Day 2' | System | 24 Aug 2020 20:15:12 |

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:14:58

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-25T12:37:40', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '8d0a8083-f30a-4e51-9e70-eb811b38bd81' | System | 25 Aug 2020 17:38:08 |
| User entered 'Does not interfere with activity (2)' | System | 25 Aug 2020 17:38:08 |

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:14:58

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-25T12:37:44', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '8d0a8083-f30a-4e51-9e70-eb811b38bd81' | System | 25 Aug 2020 17:38:08 |
| User entered 'No (N)' | System | 25 Aug 2020 17:38:08 |

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-25T12:37:47', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '8d0a8083-f30a-4e51-9e70-eb811b38bd81' | System | 25 Aug 2020 17:38:08 |
| User entered 'No (N)' | System | 25 Aug 2020 17:38:08 |

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:14:58

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-25T12:37:54', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '8d0a8083-f30a-4e51-9e70-eb811b38bd81' | System | 25 Aug 2020 17:38:08 |
| User entered 'None (1)' | System | 25 Aug 2020 17:38:08 |

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:14:58

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-25T12:38:04', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '8d0a8083-f30a-4e51-9e70-eb811b38bd81' | System | 25 Aug 2020 17:38:08 |
| User entered '25 Aug 2020 12:38' | System | 25 Aug 2020 17:38:08 |

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:14:58

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| User entered '25 Aug 2020 12:00' | System | 24 Aug 2020 20:15:12 |

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:14:58

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| User entered '26 Aug 2020 11:59' | System | 24 Aug 2020 20:15:12 |

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| Data entry locked. | System | 24 Aug 2020 20:15:12 |
| User entered 'Day 3' | System | 24 Aug 2020 20:15:12 |

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:14:58

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-26T13:18:01', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '79a284ee-76b8-4776-8001-46593ebbb64f' | System | 26 Aug 2020 18:18:35 |
| User entered 'Does not interfere with activity (2)' | System | 26 Aug 2020 18:18:35 |

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:14:58

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-26T13:18:07', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '79a284ee-76b8-4776-8001-46593ebbb64f' | System | 26 Aug 2020 18:18:35 |
| User entered 'No (N)' | System | 26 Aug 2020 18:18:35 |

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-26T13:18:12', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '79a284ee-76b8-4776-8001-46593ebbb64f' | System | 26 Aug 2020 18:18:35 |
| User entered 'No (N)' | System | 26 Aug 2020 18:18:35 |

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:14:58

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-26T13:18:15', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '79a284ee-76b8-4776-8001-46593ebbb64f' | System | 26 Aug 2020 18:18:35 |
| User entered 'None (1)' | System | 26 Aug 2020 18:18:35 |

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:14:58

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-26T13:18:29', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '79a284ee-76b8-4776-8001-46593ebbb64f' | System | 26 Aug 2020 18:18:35 |
| User entered '26 Aug 2020 13:18' | System | 26 Aug 2020 18:18:35 |

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:14:58

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| User entered '26 Aug 2020 12:00' | System | 24 Aug 2020 20:15:12 |

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:14:58

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| User entered '27 Aug 2020 11:59' | System | 24 Aug 2020 20:15:12 |

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| Data entry locked. | System | 24 Aug 2020 20:15:12 |
| User entered 'Day 4' | System | 24 Aug 2020 20:15:12 |

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:14:58

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-27T12:28:14', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '256865c5-82f8-4f2d-8ef9-f67b417429b5' | System | 27 Aug 2020 17:28:38 |
| User entered 'None (1)' | System | 27 Aug 2020 17:28:38 |

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:14:58

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-27T12:28:18', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '256865c5-82f8-4f2d-8ef9-f67b417429b5' | System | 27 Aug 2020 17:28:38 |
| User entered 'No (N)' | System | 27 Aug 2020 17:28:38 |

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-27T12:28:21', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '256865c5-82f8-4f2d-8ef9-f67b417429b5' | System | 27 Aug 2020 17:28:38 |
| User entered 'No (N)' | System | 27 Aug 2020 17:28:38 |

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:14:58

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-27T12:28:25', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '256865c5-82f8-4f2d-8ef9-f67b417429b5' | System | 27 Aug 2020 17:28:38 |
| User entered 'None (1)' | System | 27 Aug 2020 17:28:38 |

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:14:58

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-27T12:28:33', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '256865c5-82f8-4f2d-8ef9-f67b417429b5' | System | 27 Aug 2020 17:28:38 |
| User entered '27 Aug 2020 12:28' | System | 27 Aug 2020 17:28:38 |

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:14:58

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| User entered '27 Aug 2020 12:00' | System | 24 Aug 2020 20:15:12 |

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:14:58

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| User entered '28 Aug 2020 11:59' | System | 24 Aug 2020 20:15:12 |

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| Data entry locked. | System | 24 Aug 2020 20:15:12 |
| User entered 'Day 5' | System | 24 Aug 2020 20:15:12 |

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:14:58

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-28T12:09:51', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'ec06e05b-9122-46d4-840e-33e0923eb55d' | System | 28 Aug 2020 17:10:15 |
| User entered 'None (1)' | System | 28 Aug 2020 17:10:15 |

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:14:58

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-28T12:09:54', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'ec06e05b-9122-46d4-840e-33e0923eb55d' | System | 28 Aug 2020 17:10:15 |
| User entered 'No (N)' | System | 28 Aug 2020 17:10:15 |

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-28T12:09:57', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'ec06e05b-9122-46d4-840e-33e0923eb55d' | System | 28 Aug 2020 17:10:15 |
| User entered 'No (N)' | System | 28 Aug 2020 17:10:15 |

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:14:58

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-28T12:10:00', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'ec06e05b-9122-46d4-840e-33e0923eb55d' | System | 28 Aug 2020 17:10:15 |
| User entered 'None (1)' | System | 28 Aug 2020 17:10:15 |

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:14:58

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-28T12:10:11', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'ec06e05b-9122-46d4-840e-33e0923eb55d' | System | 28 Aug 2020 17:10:15 |
| User entered '28 Aug 2020 12:10' | System | 28 Aug 2020 17:10:15 |

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:14:58

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| User entered '28 Aug 2020 12:00' | System | 24 Aug 2020 20:15:12 |

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:14:58

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| User entered '29 Aug 2020 11:59' | System | 24 Aug 2020 20:15:12 |

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| Data entry locked. | System | 24 Aug 2020 20:15:12 |
| User entered 'Day 6' | System | 24 Aug 2020 20:15:12 |

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:14:58

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-29T12:17:32', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'ffee91b8-a86f-4f09-adaf-466a5683e0fc' | System | 29 Aug 2020 17:17:55 |
| User entered 'None (1)' | System | 29 Aug 2020 17:17:55 |

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:14:58

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-29T12:17:35', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'ffee91b8-a86f-4f09-adaf-466a5683e0fc' | System | 29 Aug 2020 17:17:55 |
| User entered 'No (N)' | System | 29 Aug 2020 17:17:55 |

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-29T12:17:38', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'ffee91b8-a86f-4f09-adaf-466a5683e0fc' | System | 29 Aug 2020 17:17:55 |
| User entered 'No (N)' | System | 29 Aug 2020 17:17:55 |

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:14:58

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-29T12:17:42', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'ffee91b8-a86f-4f09-adaf-466a5683e0fc' | System | 29 Aug 2020 17:17:55 |
| User entered 'None (1)' | System | 29 Aug 2020 17:17:55 |

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:14:58

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-29T12:17:50', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'ffee91b8-a86f-4f09-adaf-466a5683e0fc' | System | 29 Aug 2020 17:17:55 |
| User entered '29 Aug 2020 12:17' | System | 29 Aug 2020 17:17:55 |

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:14:58

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| User entered '29 Aug 2020 12:00' | System | 24 Aug 2020 20:15:12 |

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:14:58

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| User entered '30 Aug 2020 11:59' | System | 24 Aug 2020 20:15:12 |

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| Data entry locked. | System | 24 Aug 2020 20:15:12 |
| User entered 'Day 7' | System | 24 Aug 2020 20:15:12 |

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:14:58

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

Please select one response below

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-30T12:23:43', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'cce5ffe-4e40-4359-a663-da90ab1bed81' | System | 30 Aug 2020 17:24:06 |
| User entered 'None (1)' | System | 30 Aug 2020 17:24:06 |

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:14:58

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-30T12:23:48', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'cce5ffe-4e40-4359-a663-da90ab1bed81' | System | 30 Aug 2020 17:24:06 |
| User entered 'No (N)' | System | 30 Aug 2020 17:24:06 |

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-30T12:23:51', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'cce5ffe-4e40-4359-a663-da90ab1bed81' | System | 30 Aug 2020 17:24:06 |
| User entered 'No (N)' | System | 30 Aug 2020 17:24:06 |

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:14:58

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-30T12:23:54', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'ccef5ffe-4e40-4359-a663-da90ab1bed81' | System | 30 Aug 2020 17:24:06 |
| User entered 'None (1)' | System | 30 Aug 2020 17:24:06 |

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:14:58

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-30T12:24:02', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'cce5ffe-4e40-4359-a663-da90ab1bed81' | System | 30 Aug 2020 17:24:06 |
| User entered '30 Aug 2020 12:24' | System | 30 Aug 2020 17:24:06 |

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:14:58

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| User entered '30 Aug 2020 12:00' | System | 24 Aug 2020 20:15:12 |

US3362244

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:14:58

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| User entered '31 Aug 2020 11:59' | System | 24 Aug 2020 20:15:12 |

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| Data entry locked. | System | 24 Aug 2020 20:15:12 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 24 Aug 2020 20:15:12 |

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:14:58

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-24T15:35:03', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '27d148b1-c036-469c-b82a-25bed34c24e7' | System | 24 Aug 2020 20:35:56 |
| User entered 'No interference with activity (1)' | System | 24 Aug 2020 20:35:56 |

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:14:58

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-24T15:35:11', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '27d148b1-c036-469c-b82a-25bed34c24e7' | System | 24 Aug 2020 20:35:56 |
| User entered 'No interference with activity (1)' | System | 24 Aug 2020 20:35:56 |

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:14:58

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-24T15:35:16', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '27d148b1-c036-469c-b82a-25bed34c24e7' | System | 24 Aug 2020 20:35:56 |
| User entered 'None (0)' | System | 24 Aug 2020 20:35:56 |

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:14:58

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-24T15:35:22', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '27d148b1-c036-469c-b82a-25bed34c24e7' | System | 24 Aug 2020 20:35:56 |
| User entered 'None (0)' | System | 24 Aug 2020 20:35:56 |

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:14:58

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-24T15:35:27', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '27d148b1-c036-469c-b82a-25bed34c24e7' | System | 24 Aug 2020 20:35:56 |
| User entered 'None (0)' | System | 24 Aug 2020 20:35:56 |

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:14:58

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-24T15:35:30', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '27d148b1-c036-469c-b82a-25bed34c24e7' | System | 24 Aug 2020 20:35:56 |
| User entered 'None (0)' | System | 24 Aug 2020 20:35:56 |

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:14:58

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) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-24T15:35:36', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '27d148b1-c036-469c-b82a-25bed34c24e7' | System | 24 Aug 2020 20:35:56 |
| User entered 'No (N)' | System | 24 Aug 2020 20:35:56 |

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:14:58

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-24T15:35:46', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '27d148b1-c036-469c-b82a-25bed34c24e7' | System | 24 Aug 2020 20:35:56 |
| User entered '24 Aug 2020 15:35' | System | 24 Aug 2020 20:35:56 |

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:14:58

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| User entered '24 Aug 2020 15:18' | System | 24 Aug 2020 20:15:12 |

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:14:58

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| User entered '24 Aug 2020 17:48' | System | 24 Aug 2020 20:15:12 |

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| Data entry locked. | System | 24 Aug 2020 20:15:12 |
| User entered 'Day 1, after vaccination (at home)' | System | 24 Aug 2020 20:15:12 |

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:14:58

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-24T20:26:44', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'e4c42146-feaf-43eb-9163-ebd734977334' | System | 25 Aug 2020 01:29:09 |
| User entered 'None (0)' | System | 25 Aug 2020 01:29:09 |

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:14:58

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-24T20:26:55', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'e4c42146-feaf-43eb-9163-ebd734977334' | System | 25 Aug 2020 01:29:09 |
| User entered 'No interference with activity (1)' | System | 25 Aug 2020 01:29:09 |

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:14:58

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-24T20:27:02', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'e4c42146-feaf-43eb-9163-ebd734977334' | System | 25 Aug 2020 01:29:09 |
| User entered 'None (0)' | System | 25 Aug 2020 01:29:09 |

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:14:58

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-24T20:27:13', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'e4c42146-feaf-43eb-9163-ebd734977334' | System | 25 Aug 2020 01:29:09 |
| User entered 'None (0)' | System | 25 Aug 2020 01:29:09 |

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:14:58

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-24T20:27:24', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'e4c42146-feaf-43eb-9163-ebd734977334' | System | 25 Aug 2020 01:29:09 |
| User entered 'None (0)' | System | 25 Aug 2020 01:29:09 |

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:14:58

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-24T20:27:34', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'e4c42146-feaf-43eb-9163-ebd734977334' | System | 25 Aug 2020 01:29:09 |
| User entered 'None (0)' | System | 25 Aug 2020 01:29:09 |

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:14:58

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) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-24T20:28:48', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'e4c42146-feaf-43eb-9163-ebd734977334' | System | 25 Aug 2020 01:29:09 |
| User entered 'No (N)' | System | 25 Aug 2020 01:29:09 |

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:14:58

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-24T20:29:04', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'e4c42146-feaf-43eb-9163-ebd734977334' | System | 25 Aug 2020 01:29:09 |
| User entered '24 Aug 2020 20:29' | System | 25 Aug 2020 01:29:09 |

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:14:58

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| User entered '24 Aug 2020 18:43' | System | 24 Aug 2020 20:15:12 |

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:14:58

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| User entered '25 Aug 2020 11:59' | System | 24 Aug 2020 20:15:12 |

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| Data entry locked. | System | 24 Aug 2020 20:15:12 |
| User entered 'Day 2' | System | 24 Aug 2020 20:15:12 |

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:14:58

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-25T12:38:12', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '50496003-b7f8-4a4b-a079-3e93b7b3742d' | System | 25 Aug 2020 17:39:12 |
| User entered 'None (0)' | System | 25 Aug 2020 17:39:12 |

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:14:58

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-25T12:38:22', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '50496003-b7f8-4a4b-a079-3e93b7b3742d' | System | 25 Aug 2020 17:39:12 |
| User entered 'No interference with activity (1)' | System | 25 Aug 2020 17:39:12 |

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:14:58

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-25T12:38:31', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '50496003-b7f8-4a4b-a079-3e93b7b3742d' | System | 25 Aug 2020 17:39:12 |
| User entered 'None (0)' | System | 25 Aug 2020 17:39:12 |

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:14:58

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-25T12:38:38', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '50496003-b7f8-4a4b-a079-3e93b7b3742d' | System | 25 Aug 2020 17:39:12 |
| User entered 'None (0)' | System | 25 Aug 2020 17:39:12 |

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:14:58

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-25T12:38:41', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '50496003-b7f8-4a4b-a079-3e93b7b3742d' | System | 25 Aug 2020 17:39:12 |
| User entered 'None (0)' | System | 25 Aug 2020 17:39:12 |

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:14:58

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-25T12:38:44', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '50496003-b7f8-4a4b-a079-3e93b7b3742d' | System | 25 Aug 2020 17:39:12 |
| User entered 'None (0)' | System | 25 Aug 2020 17:39:12 |

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:14:58

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) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-25T12:38:50', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '50496003-b7f8-4a4b-a079-3e93b7b3742d' | System | 25 Aug 2020 17:39:12 |
| User entered 'No (N)' | System | 25 Aug 2020 17:39:12 |

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:14:58

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-25T12:39:09', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '50496003-b7f8-4a4b-a079-3e93b7b3742d' | System | 25 Aug 2020 17:39:12 |
| User entered '25 Aug 2020 12:39' | System | 25 Aug 2020 17:39:12 |

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:14:58

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| User entered '25 Aug 2020 12:00' | System | 24 Aug 2020 20:15:12 |

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:14:58

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| User entered '26 Aug 2020 11:59' | System | 24 Aug 2020 20:15:12 |

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| Data entry locked. | System | 24 Aug 2020 20:15:12 |
| User entered 'Day 3' | System | 24 Aug 2020 20:15:12 |

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:14:58

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-26T13:18:38', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '1e3b00e7-2c41-4ba1-840e-9767d697d87a' | System | 26 Aug 2020 18:19:17 |
| User entered 'None (0)' | System | 26 Aug 2020 18:19:17 |

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:14:58

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-26T13:18:48', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '1e3b00e7-2c41-4ba1-840e-9767d697d87a' | System | 26 Aug 2020 18:19:17 |
| User entered 'None (0)' | System | 26 Aug 2020 18:19:17 |

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:14:58

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-26T13:18:52', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '1e3b00e7-2c41-4ba1-840e-9767d697d87a' | System | 26 Aug 2020 18:19:17 |
| User entered 'None (0)' | System | 26 Aug 2020 18:19:17 |

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:14:58

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-26T13:18:55', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '1e3b00e7-2c41-4ba1-840e-9767d697d87a' | System | 26 Aug 2020 18:19:17 |
| User entered 'None (0)' | System | 26 Aug 2020 18:19:17 |

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:14:58

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-26T13:18:58', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '1e3b00e7-2c41-4ba1-840e-9767d697d87a' | System | 26 Aug 2020 18:19:17 |
| User entered 'None (0)' | System | 26 Aug 2020 18:19:17 |

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:14:58

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-26T13:19:00', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '1e3b00e7-2c41-4ba1-840e-9767d697d87a' | System | 26 Aug 2020 18:19:17 |
| User entered 'None (0)' | System | 26 Aug 2020 18:19:17 |

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:14:58

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) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-26T13:19:04', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '1e3b00e7-2c41-4ba1-840e-9767d697d87a' | System | 26 Aug 2020 18:19:17 |
| User entered 'No (N)' | System | 26 Aug 2020 18:19:17 |

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:14:58

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-26T13:19:15', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '1e3b00e7-2c41-4ba1-840e-9767d697d87a' | System | 26 Aug 2020 18:19:17 |
| User entered '26 Aug 2020 13:19' | System | 26 Aug 2020 18:19:17 |

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:14:58

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| User entered '26 Aug 2020 12:00' | System | 24 Aug 2020 20:15:12 |

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:14:58

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| User entered '27 Aug 2020 11:59' | System | 24 Aug 2020 20:15:12 |

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| Data entry locked. | System | 24 Aug 2020 20:15:12 |
| User entered 'Day 4' | System | 24 Aug 2020 20:15:12 |

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:14:58

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-27T12:28:40', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '492cea4b-b6c0-4373-b198-3214b99ee985' | System | 27 Aug 2020 17:29:08 |
| User entered 'None (0)' | System | 27 Aug 2020 17:29:08 |

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:14:58

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-27T12:28:43', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '492cea4b-b6c0-4373-b198-3214b99ee985' | System | 27 Aug 2020 17:29:08 |
| User entered 'None (0)' | System | 27 Aug 2020 17:29:08 |

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:14:58

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-27T12:28:46', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '492cea4b-b6c0-4373-b198-3214b99ee985' | System | 27 Aug 2020 17:29:08 |
| User entered 'None (0)' | System | 27 Aug 2020 17:29:08 |

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:14:58

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-27T12:28:49', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '492cea4b-b6c0-4373-b198-3214b99ee985' | System | 27 Aug 2020 17:29:08 |
| User entered 'None (0)' | System | 27 Aug 2020 17:29:08 |

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:14:58

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-27T12:28:51', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '492cea4b-b6c0-4373-b198-3214b99ee985' | System | 27 Aug 2020 17:29:08 |
| User entered 'None (0)' | System | 27 Aug 2020 17:29:08 |

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:14:58

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-27T12:28:54', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '492cea4b-b6c0-4373-b198-3214b99ee985' | System | 27 Aug 2020 17:29:08 |
| User entered 'None (0)' | System | 27 Aug 2020 17:29:08 |

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:14:58

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) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-27T12:28:57', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '492cea4b-b6c0-4373-b198-3214b99ee985' | System | 27 Aug 2020 17:29:08 |
| User entered 'No (N)' | System | 27 Aug 2020 17:29:08 |

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:14:58

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-27T12:29:04', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '492cea4b-b6c0-4373-b198-3214b99ee985' | System | 27 Aug 2020 17:29:08 |
| User entered '27 Aug 2020 12:29' | System | 27 Aug 2020 17:29:08 |

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:14:58

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| User entered '27 Aug 2020 12:00' | System | 24 Aug 2020 20:15:12 |

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:14:58

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| User entered '28 Aug 2020 11:59' | System | 24 Aug 2020 20:15:12 |

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| Data entry locked. | System | 24 Aug 2020 20:15:12 |
| User entered 'Day 5' | System | 24 Aug 2020 20:15:12 |

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:14:58

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-28T12:10:16', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '4a8d92ac-12f1-45ce-834e-ef783d262947' | System | 28 Aug 2020 17:10:48 |
| User entered 'None (0)' | System | 28 Aug 2020 17:10:48 |

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:14:58

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-28T12:10:19', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '4a8d92ac-12f1-45ce-834e-ef783d262947' | System | 28 Aug 2020 17:10:48 |
| User entered 'None (0)' | System | 28 Aug 2020 17:10:48 |

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:14:58

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-28T12:10:21', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '4a8d92ac-12f1-45ce-834e-ef783d262947' | System | 28 Aug 2020 17:10:48 |
| User entered 'None (0)' | System | 28 Aug 2020 17:10:48 |

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:14:58

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-28T12:10:23', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '4a8d92ac-12f1-45ce-834e-ef783d262947' | System | 28 Aug 2020 17:10:48 |
| User entered 'None (0)' | System | 28 Aug 2020 17:10:48 |

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:14:58

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-28T12:10:25', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '4a8d92ac-12f1-45ce-834e-ef783d262947' | System | 28 Aug 2020 17:10:48 |
| User entered 'None (0)' | System | 28 Aug 2020 17:10:48 |

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:14:58

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-28T12:10:27', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '4a8d92ac-12f1-45ce-834e-ef783d262947' | System | 28 Aug 2020 17:10:48 |
| User entered 'None (0)' | System | 28 Aug 2020 17:10:48 |

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:14:58

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) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-28T12:10:31', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '4a8d92ac-12f1-45ce-834e-ef783d262947' | System | 28 Aug 2020 17:10:48 |
| User entered 'No (N)' | System | 28 Aug 2020 17:10:48 |

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:14:58

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-28T12:10:41', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '4a8d92ac-12f1-45ce-834e-ef783d262947' | System | 28 Aug 2020 17:10:48 |
| User entered '28 Aug 2020 12:10' | System | 28 Aug 2020 17:10:48 |

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:14:58

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| User entered '28 Aug 2020 12:00' | System | 24 Aug 2020 20:15:12 |

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:14:58

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| User entered '29 Aug 2020 11:59' | System | 24 Aug 2020 20:15:12 |

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| Data entry locked. | System | 24 Aug 2020 20:15:12 |
| User entered 'Day 6' | System | 24 Aug 2020 20:15:12 |

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:14:58

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-29T12:17:57', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '9c87bf2c-d9e0-45eb-8395-66957abf413d' | System | 29 Aug 2020 17:18:42 |
| User entered 'None (0)' | System | 29 Aug 2020 17:18:42 |

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:14:58

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-29T12:18:01', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '9c87bf2c-d9e0-45eb-8395-66957abf413d' | System | 29 Aug 2020 17:18:42 |
| User entered 'None (0)' | System | 29 Aug 2020 17:18:42 |

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:14:58

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-29T12:18:04', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '9c87bf2c-d9e0-45eb-8395-66957abf413d' | System | 29 Aug 2020 17:18:42 |
| User entered 'None (0)' | System | 29 Aug 2020 17:18:42 |

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:14:58

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-29T12:18:07', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '9c87bf2c-d9e0-45eb-8395-66957abf413d' | System | 29 Aug 2020 17:18:42 |
| User entered 'None (0)' | System | 29 Aug 2020 17:18:42 |

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:14:58

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-29T12:18:10', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '9c87bf2c-d9e0-45eb-8395-66957abf413d' | System | 29 Aug 2020 17:18:42 |
| User entered 'None (0)' | System | 29 Aug 2020 17:18:42 |

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:14:58

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-29T12:18:12', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '9c87bf2c-d9e0-45eb-8395-66957abf413d' | System | 29 Aug 2020 17:18:42 |
| User entered 'None (0)' | System | 29 Aug 2020 17:18:42 |

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:14:58

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) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-29T12:18:25', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '9c87bf2c-d9e0-45eb-8395-66957abf413d' | System | 29 Aug 2020 17:18:42 |
| User entered 'No (N)' | System | 29 Aug 2020 17:18:42 |

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:14:58

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-29T12:18:34', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '9c87bf2c-d9e0-45eb-8395-66957abf413d' | System | 29 Aug 2020 17:18:42 |
| User entered '29 Aug 2020 12:18' | System | 29 Aug 2020 17:18:42 |

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:14:58

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| User entered '29 Aug 2020 12:00' | System | 24 Aug 2020 20:15:12 |

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:14:58

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| User entered '30 Aug 2020 11:59' | System | 24 Aug 2020 20:15:12 |

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| Data entry locked. | System | 24 Aug 2020 20:15:12 |
| User entered 'Day 7' | System | 24 Aug 2020 20:15:12 |

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:14:58

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-30T12:24:25', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'c6820e91-f606-4223-9593-60da0d3c930e' User entered 'None (0)' | System | 30 Aug 2020 17:24:51 |
| | System | 30 Aug 2020 17:24:51 |

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:14:58

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-30T12:24:28', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'c6820e91-f606-4223-9593-60da0d3c930e' User entered 'None (0)' | System | 30 Aug 2020 17:24:51 |
| | System | 30 Aug 2020 17:24:51 |

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:14:58

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-30T12:24:30', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'c6820e91-f606-4223-9593-60da0d3c930e' User entered 'None (0)' | System | 30 Aug 2020 17:24:51 |
| | System | 30 Aug 2020 17:24:51 |

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:14:58

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-30T12:24:33', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'c6820e91-f606-4223-9593-60da0d3c930e' User entered 'None (0)' | System | 30 Aug 2020 17:24:51 |
| | System | 30 Aug 2020 17:24:51 |

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:14:58

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-30T12:24:35', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'c6820e91-f606-4223-9593-60da0d3c930e' User entered 'None (0)' | System | 30 Aug 2020 17:24:51 |
| | System | 30 Aug 2020 17:24:51 |

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:14:58

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-30T12:24:38', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'c6820e91-f606-4223-9593-60da0d3c930e' User entered 'None (0)' | System | 30 Aug 2020 17:24:51 |
| | System | 30 Aug 2020 17:24:51 |

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:14:58

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) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-30T12:24:41', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'c6820e91-f606-4223-9593-60da0d3c930e' | System | 30 Aug 2020 17:24:51 |
| User entered 'No (N)' | System | 30 Aug 2020 17:24:51 |

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:14:58

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-08-30T12:24:49', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'c6820e91-f606-4223-9593-60da0d3c930e' | System | 30 Aug 2020 17:24:51 |
| User entered '30 Aug 2020 12:24' | System | 30 Aug 2020 17:24:51 |

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:14:58

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| User entered '30 Aug 2020 12:00' | System | 24 Aug 2020 20:15:12 |

US3362244

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:14:58

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| User entered '31 Aug 2020 11:59' | System | 24 Aug 2020 20:15:12 |

US3362244

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:58

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered 'Yes (Y)' | Crystal Rowell (b) (4) | 31 Aug 2020 23:29:46 |

US3362244

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:58

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered '31 Aug 2020' | Crystal Rowell (b) (4) | 31 Aug 2020 23:29:46 |

US3362244

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:58

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered 'Contact Made (CONTACT MADE)' | Crystal Rowell (b) (4) | 31 Aug 2020 23:29:46 |

US3362244

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:58

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered empty. | Crystal Rowell (b) (4) | 31 Aug 2020 23:29:46 |

US3362244

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:14:58

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered 'Yes (Y)' | Crystal Rowell (b) (4) | 31 Aug 2020 23:45:13 |

US3362244

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:14:58

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User entered 'I' | System | 31 Aug 2020 23:45:13 |

US3362244

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:58

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 08 Sep 2020 22:32:29 |

US3362244

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:58

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered '08 Sep 2020' | (b) (4), (b) (6) | 08 Sep 2020 22:32:29 |

US3362244

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:58

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) (b) (4), (b) (6) | 08 Sep 2020 22:32:29 |

US3362244

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:58

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 08 Sep 2020 22:32:29 |

US3362244

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:14:58

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 08 Sep 2020 22:33:07 |

US3362244

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:14:58

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User entered 'I' | System | 08 Sep 2020 22:33:07 |

US3362244

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:58

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 14 Sep 2020 17:03:57 |

US3362244

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:58

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered '14 Sep 2020' | (b) (4) (b) (4), (b) (6) | 14 Sep 2020 17:03:57 |

US3362244

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:58

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) (b) (4), (b) (6) | 14 Sep 2020 17:03:57 |

US3362244

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:58

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 14 Sep 2020 17:03:57 |

US3362244

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:14:58

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 14 Sep 2020 17:04:01 |

US3362244

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:14:58

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User entered 'I' | System | 14 Sep 2020 17:04:01 |

US3362244

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:14:58

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 23 Sep 2020 21:52:34 |

US3362244

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered '23 Sep 2020' | (b) (4) (b) (4), (b) (6) | 23 Sep 2020 21:52:34 |

US3362244

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered 'Clinic (Clinic)' | (b) (4) (b) (4), (b) (6) | 23 Sep 2020 21:52:34 |

US3362244

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:14:58

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User entered 'VISIT2' | System | 23 Sep 2020 21:52:34 |

US3362244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:58

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User accepted default value 'Pre-Dose (PREDOSE)' | (b) (4), (b) (6) | 23 Sep 2020 21:54:47 |

US3362244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:58

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 23 Sep 2020 21:54:47 |

US3362244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:58

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered '23 Sep 2020' | (b) (4) (b) (4), (b) (6) | 23 Sep 2020 21:54:47 |

US3362244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered '14:20' | (b) (4) (b) (4), (b) (6) | 23 Sep 2020 21:54:47 |

US3362244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User entered '23 Sep 2020 14:20' | System | 23 Sep 2020 21:54:47 |

US3362244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:58

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered '37.5' C | (b) (4) (b) (4), (b) (6) | 23 Sep 2020 21:54:47 |

US3362244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:58

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered 'Oral (Oral)' | (b) (4) (b) (4), (b) (6) | 23 Sep 2020 21:54:47 |

US3362244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:58

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 23 Sep 2020 21:54:47 |

US3362244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:58

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered '90' | (b) (4) (b) (4), (b) (6) | 23 Sep 2020 21:54:47 |

US3362244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:58

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User entered 'bpm' | System | 23 Sep 2020 21:54:47 |

US3362244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered '16' | (b) (4) (b) (4), (b) (6) | 23 Sep 2020 21:54:47 |

US3362244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:58

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User entered 'breaths/min' | System | 23 Sep 2020 21:54:47 |

US3362244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered '110' | (b) (4) (b) (4), (b) (6) | 23 Sep 2020 21:54:47 |

US3362244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:58

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User entered 'mmHg' | System | 23 Sep 2020 21:54:47 |

US3362244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered '75' | (b) (4) (b) (4), (b) (6) | 23 Sep 2020 21:54:47 |

US3362244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:58

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User entered 'mmHg' | System | 23 Sep 2020 21:54:47 |

US3362244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:58

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User accepted default value 'Post-Dose (POSTDOSE)' | (b) (4), (b) (6) | 23 Sep 2020 21:54:47 |

US3362244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:58

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4) | 26 Sep 2020 20:32:43 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 23 Sep 2020 21:54:47 |

US3362244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:58

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered empty; reason for change Data Entry Error | (b) (4) | 26 Sep 2020 20:32:43 |
| User entered '23 Sep 2020' | Amy Thomassie (b) (4) | 23 Sep 2020 21:54:47 |
| | (b) (4), (b) (6) | |

US3362244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4) | 26 Sep 2020 20:32:43 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). | System | 26 Sep 2020 20:32:43 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 23 Sep 2020 21:54:47 |
| User entered empty. | (b) (4), (b) (6) | 23 Sep 2020 21:54:47 |

US3362244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User entered empty. | System | 23 Sep 2020 21:54:47 |

US3362244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:58

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4) System | 26 Sep 2020 20:32:43 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). | | 26 Sep 2020 20:32:43 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 23 Sep 2020 21:54:47 |
| User entered empty. | (b) (4), (b) (6) | 23 Sep 2020 21:54:47 |

US3362244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:58

[Route of measurement](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 23 Sep 2020 21:54:47 |

US3362244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:58

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 23 Sep 2020 21:54:47 |

US3362244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:58

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4) System | 26 Sep 2020 20:32:43 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). | | 26 Sep 2020 20:32:43 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 23 Sep 2020 21:54:47 |
| User entered empty. | (b) (4), (b) (6) | 23 Sep 2020 21:54:47 |

US3362244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:58

[Pulse units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User entered empty. | System | 23 Sep 2020 21:54:47 |

US3362244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4) System | 26 Sep 2020 20:32:43 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). | | 26 Sep 2020 20:32:43 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 23 Sep 2020 21:54:47 |
| User entered empty. | (b) (4), (b) (6) | 23 Sep 2020 21:54:47 |

US3362244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:58

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User entered empty. | System | 23 Sep 2020 21:54:47 |

US3362244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4) | 26 Sep 2020 20:32:43 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). | System | 26 Sep 2020 20:32:43 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 23 Sep 2020 21:54:47 |
| User entered empty. | (b) (4), (b) (6) | 23 Sep 2020 21:54:47 |

US3362244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:58

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User entered empty. | System | 23 Sep 2020 21:54:47 |

US3362244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4) System | 26 Sep 2020 20:32:43 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). | | 26 Sep 2020 20:32:43 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 23 Sep 2020 21:54:47 |
| User entered empty. | (b) (4), (b) (6) | 23 Sep 2020 21:54:47 |

US3362244

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:58

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User entered empty. | System | 23 Sep 2020 21:54:47 |

US3362244

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:14:58

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered 'Yes (Y)' | Amy Thomassie (b) (4) | 26 Sep 2020 20:33:48 |

US3362244

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:14:58

Date of examination (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered '23 Sep 2020' | Amy Thomassie (b) (4) | 26 Sep 2020 20:33:48 |

US3362244

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:14:58

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered 'No (N)' | Amy Thomassie (b) (4) | 26 Sep 2020 20:35:10 |

US3362244

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:14:58

[If No, reason not given](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered 'Other (OTHER)' reason for change: Data Entry Error | Crystal Rowell (b) (4) | 11 Jan 2021 23:12:22 |
| User entered 'Withdrawal of Consent by Participant (WITHDRAWAL OF CONSENT)' reason for change: Data Entry Error | Crystal Rowell (b) (4) | 02 Oct 2020 19:14:37 |
| User entered 'Other (OTHER)' | Amy Thomassie (b) (4) | 26 Sep 2020 20:35:10 |

US3362244

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered 'PATIENT DECLINED second dose DUE TO ORTHOPEDIC SURGERY BEING NEEDED' reason for change: Data Entry Error | Crystal Rowell (b) (4) | 11 Jan 2021 23:12:22 |
| User closed query 'Per CDM: Thank you for your response. However, please update forms as fracture and/or surgery information is not present. Thank you' (Site from DM). | (b) (4), (b) (6) | 15 Oct 2020 20:10:04 |
| Query 'Per CDM: Thank you for your response. However, please update forms as fracture and/or surgery information is not present. Thank you' answered with 'pending medical records. Will update as soon as recieved.' (Site from DM). | (b) (4), (b) (6) | 14 Oct 2020 22:26:52 |
| User opened query 'Per CDM: Thank you for your response. However, please update forms as fracture and/or surgery information is not present. Thank you' (Site from DM). | (b) (4), (b) (6) | 08 Oct 2020 19:40:17 |
| User closed query 'Per CDM: Please complete applicable AE form for "severe elbow fracture" and dosing discontinuation form if applicable. Thank you.' (Site from DM). | (b) (4), (b) (6) | 08 Oct 2020 19:36:48 |
| Query 'Per CDM: Please complete applicable AE form for "severe elbow fracture" and dosing discontinuation form if applicable. Thank you.' answered with 'updated ' (Site from DM). | Crystal Rowell (b) (4) | 02 Oct 2020 19:14:44 |
| User entered 'patient declined due to orthopedic surgery being needed' reason for change: Data Entry Error | Crystal Rowell (b) (4) | 02 Oct 2020 19:14:37 |
| User opened query 'Per CDM: Please complete applicable AE form for "severe elbow fracture" and dosing discontinuation form if applicable. Thank you.' (Site from DM). | (b) (4), (b) (6) | 30 Sep 2020 14:54:19 |
| User entered 'participant has severe elbow fracture with surgery pending. participant declined vaccination.' | Amy Thomassie (b) (4) | 26 Sep 2020 20:35:10 |

US3362244

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:14:58

[What was the study treatment?](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User entered empty. | System | 26 Sep 2020 20:35:10 |

US3362244

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:14:58

What was the treatment date? (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered empty. | Amy Thomassie (b) (4) | 26 Sep 2020 20:35:10 |

US3362244

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered empty. | Amy Thomassie (b) (4) | 26 Sep 2020 20:35:10 |

US3362244

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User entered empty. | System | 26 Sep 2020 20:35:10 |

US3362244

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered empty. | Amy Thomassie (b) (4) | 26 Sep 2020 20:35:10 |

US3362244

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User entered empty. | System | 26 Sep 2020 20:35:10 |

US3362244

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:14:58

What was the route of administration for the study treatment?

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User entered empty. | System | 26 Sep 2020 20:35:10 |

US3362244

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:14:58

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered 'Yes (Y)' | Amy Thomassie (b) (4) | 26 Sep 2020 20:35:46 |

US3362244

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:14:58

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered '23 Sep 2020' | Amy Thomassie (b) (4) | 26 Sep 2020 20:35:46 |

US3362244

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:14:58

Collection time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered '14:35' | Amy Thomassie (b) (4) | 26 Sep 2020 20:35:46 |

US3362244

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User entered '23 Sep 2020 14:35' | System | 26 Sep 2020 20:35:46 |

US3362244

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:14:58

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered '23 Sep 2020' | Amy Thomassie (b) (4) | 26 Sep 2020 20:36:03 |

US3362244

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:14:58

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | Amy Thomassie (b) (4) | 26 Sep 2020 20:36:03 |

US3362244

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:14:58

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered 'Yes (Y)' | Amy Thomassie (b) (4) | 26 Sep 2020 20:36:03 |

US3362244

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:14:58

[Collection time \(00:00 - 23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered '14:42' | Amy Thomassie (b) (4) | 26 Sep 2020 20:36:03 |

US3362244

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User entered '23 Sep 2020 14:42' | System | 26 Sep 2020 20:36:03 |

US3362244

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:14:58

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | Amy Thomassie (b) (4) | 26 Sep 2020 20:36:03 |

US3362244

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:14:58

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered 'No (N)' | Amy Thomassie (b) (4) | 26 Sep 2020 20:36:03 |

US3362244

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:14:58

[Collection time \(00:00 - 23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered empty. | Amy Thomassie (b) (4) | 26 Sep 2020 20:36:03 |

US3362244

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User entered empty. | System | 26 Sep 2020 20:36:03 |

US3362244

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:14:58

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered 'Yes (Y)' | Amy Thomassie (b) (4) | 26 Sep 2020 20:36:17 |

US3362244

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:14:58

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User entered 'I' | System | 26 Sep 2020 20:36:17 |

US3362244

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:58

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered 'Yes (Y)' | Crystal Rowell (b) (4) | 02 Oct 2020 19:39:42 |

US3362244

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:58

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered '02 Oct 2020' | Crystal Rowell (b) (4) | 02 Oct 2020 19:39:42 |

US3362244

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:58

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered 'Contact Made (CONTACT MADE)' | Crystal Rowell (b) (4) | 02 Oct 2020 19:39:42 |

US3362244

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:58

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered empty. | Crystal Rowell (b) (4) | 02 Oct 2020 19:39:42 |

US3362244

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:14:58

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered 'Yes (Y)' | Crystal Rowell (b) (4) | 02 Oct 2020 19:39:46 |

US3362244

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:14:58

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User entered 'I' | System | 02 Oct 2020 19:39:46 |

US3362244

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:58

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 14 Oct 2020 22:56:56 |

US3362244

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:58

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered '07 Oct 2020' | (b) (4), (b) (6) | 14 Oct 2020 22:56:56 |

US3362244

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:58

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4), (b) (6) | 14 Oct 2020 22:56:56 |

US3362244

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:58

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered empty. | (b) (4), (b) (6) | 14 Oct 2020 22:56:56 |

US3362244

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:14:58

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 14 Oct 2020 22:57:00 |

US3362244

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:14:58

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User entered 'I' | System | 14 Oct 2020 22:57:00 |

US3362244

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:58

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 14 Oct 2020 22:57:18 |

US3362244

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:58

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered '14 Oct 2020' | (b) (4), (b) (6) | 14 Oct 2020 22:57:18 |

US3362244

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:58

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4), (b) (6) | 14 Oct 2020 22:57:18 |

US3362244

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:58

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered empty. | (b) (4), (b) (6) | 14 Oct 2020 22:57:18 |

US3362244

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:14:58

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 14 Oct 2020 22:57:22 |

US3362244

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:14:58

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User entered 'I' | System | 14 Oct 2020 22:57:22 |

US3362244

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:14:58

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered 'Yes (Y)' | Crystal Rowell (b) (4) | 12 Nov 2020 19:54:17 |

US3362244

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered '28 Oct 2020' | Crystal Rowell (b) (4) | 12 Nov 2020 19:54:17 |

US3362244

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|--------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered 'Clinic (Clinic)' | Crystal Rowell (b) (4) | 12 Nov 2020 19:54:17 |

US3362244

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:14:58

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User entered 'VISIT3' | System | 12 Nov 2020 19:54:17 |

US3362244

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:58

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered 'Yes (Y)' | Crystal Rowell (b) (4) | 12 Nov 2020 19:55:22 |

US3362244

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:58

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered '28 Oct 2020' | Crystal Rowell (b) (4) | 12 Nov 2020 19:55:22 |

US3362244

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered '12:38' | Crystal Rowell (b) (4) | 12 Nov 2020 19:55:22 |

US3362244

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User entered '28 Oct 2020 12:38' | System | 12 Nov 2020 19:55:22 |

US3362244

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:58

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered '36.9' C | Crystal Rowell (b) (4) | 12 Nov 2020 19:55:22 |

US3362244

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:58

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered 'Oral (Oral)' | Crystal Rowell (b) (4) | 12 Nov 2020 19:55:22 |

US3362244

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:58

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered empty. | Crystal Rowell (b) (4) | 12 Nov 2020 19:55:22 |

US3362244

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:58

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered '90' | Crystal Rowell (b) (4) | 12 Nov 2020 19:55:22 |

US3362244

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:58

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User entered 'bpm' | System | 12 Nov 2020 19:55:22 |

US3362244

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered '18' | Crystal Rowell (b) (4) | 12 Nov 2020 19:55:22 |

US3362244

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:58

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User entered 'breaths/min' | System | 12 Nov 2020 19:55:22 |

US3362244

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered '127' | Crystal Rowell (b) (4) | 12 Nov 2020 19:55:22 |

US3362244

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:58

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User entered 'mmHg' | System | 12 Nov 2020 19:55:22 |

US3362244

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered '90' | Crystal Rowell (b) (4) | 12 Nov 2020 19:55:22 |

US3362244

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:58

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User entered 'mmHg' | System | 12 Nov 2020 19:55:22 |

US3362244

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:58

[Height \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| | | |

US3362244

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:58

[Weight \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| | | |

US3362244

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:14:58

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered 'Yes (Y)' | Crystal Rowell (b) (4) | 12 Nov 2020 19:55:30 |

US3362244

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:14:58

Date of examination (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered '28 Oct 2020' | Crystal Rowell (b) (4) | 12 Nov 2020 19:55:30 |

US3362244

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:14:58

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered 'Yes (Y)' | Crystal Rowell (b) (4) | 12 Nov 2020 19:55:51 |

US3362244

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:14:58

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered '28 Oct 2020' | Crystal Rowell (b) (4) | 12 Nov 2020 19:55:51 |

US3362244

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:14:58

Collection time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered '12:50' | Crystal Rowell (b) (4) | 12 Nov 2020 19:55:51 |

US3362244

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User entered '28 Oct 2020 12:50' | System | 12 Nov 2020 19:55:51 |

US3362244

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:14:58

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 20 Feb 2021 18:06:31 |
| User entered 'Yes (Y)' | Crystal Rowell (b) (4) | 12 Nov 2020 19:55:55 |

US3362244

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:14:58

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User entered 'I' | System | 12 Nov 2020 19:55:55 |

US3362244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| Data entry locked. | System | 24 Aug 2020 20:15:12 |
| User entered 'Day 64' | System | 24 Aug 2020 20:15:12 |

US3362244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[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) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-10-26T13:02:17', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '027ae8be-5339-4266-9394-f78f0d8b07ae' | System | 26 Oct 2020 18:03:34 |
| User entered 'Yes (Y)' | System | 26 Oct 2020 18:03:34 |

US3362244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

Have you been exposed to someone with 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) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-10-26T13:02:27', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '027ae8be-5339-4266-9394-f78f0d8b07ae' | System | 26 Oct 2020 18:03:34 |
| User entered 'No (N)' | System | 26 Oct 2020 18:03:34 |

US3362244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-10-26T13:02:33', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '027ae8be-5339-4266-9394-f78f0d8b07ae' | System | 26 Oct 2020 18:03:34 |
| User entered 'No (N)' | System | 26 Oct 2020 18:03:34 |

US3362244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-10-26T13:02:45', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '027ae8be-5339-4266-9394-f78f0d8b07ae' | System | 26 Oct 2020 18:03:34 |
| User entered 'Yes (Y)' | System | 26 Oct 2020 18:03:34 |

US3362244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-10-26T13:02:57', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '027ae8be-5339-4266-9394-f78f0d8b07ae' | System | 26 Oct 2020 18:03:34 |
| User entered 'I confirm I have read this message and will call the study clinic immediately (9)' | System | 26 Oct 2020 18:03:34 |

US3362244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-10-26T13:03:21', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '027ae8be-5339-4266-9394-f78f0d8b07ae' | System | 26 Oct 2020 18:03:34 |
| User entered '26 Oct 2020 13:03:21' | System | 26 Oct 2020 18:03:34 |

US3362244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| Data entry locked. | System | 24 Aug 2020 20:15:12 |
| User entered '24 Oct 2020 00:01' | System | 24 Aug 2020 20:15:12 |

US3362244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| Data entry locked. | System | 24 Aug 2020 20:15:12 |
| User entered '28 Oct 2020 23:59' | System | 24 Aug 2020 20:15:12 |

US3362244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| Data entry locked. | System | 24 Aug 2020 20:15:12 |
| User entered 'Day 71' | System | 24 Aug 2020 20:15:12 |

US3362244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[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) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-10-31T09:18:53', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'b39bd4d8-8405-4ac1-97bb-84a1330ea106' | System | 31 Oct 2020 14:19:22 |
| User entered 'No (N)' | System | 31 Oct 2020 14:19:22 |

US3362244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Have you been exposed to someone with 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) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-10-31T09:19:00', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'b39bd4d8-8405-4ac1-97bb-84a1330ea106' | System | 31 Oct 2020 14:19:22 |
| User entered 'No (N)' | System | 31 Oct 2020 14:19:22 |

US3362244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2020-10-31T09:19:18', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'b39bd4d8-8405-4ac1-97bb-84a1330ea106' | System | 31 Oct 2020 14:19:22 |
| User entered '31 Oct 2020 09:19:18' | System | 31 Oct 2020 14:19:22 |

US3362244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| Data entry locked. | System | 24 Aug 2020 20:15:12 |
| User entered '31 Oct 2020 00:01' | System | 24 Aug 2020 20:15:12 |

US3362244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 00:59:39 |
| Data entry locked. | System | 24 Aug 2020 20:15:12 |
| User entered '04 Nov 2020 23:59' | System | 24 Aug 2020 20:15:12 |

US3362244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 10:58:19 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 20 Nov 2020 01:55:21 |
| Data entry locked. | System | 24 Aug 2020 20:15:12 |
| User entered 'Day 78' | System | 24 Aug 2020 20:15:12 |

US3362244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 10:58:19 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 10:58:19 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 10:58:19 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 10:58:19 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

Fever (Temperature \geq 100.4°F/38°C)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 10:58:19 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Chills](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 10:58:19 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Cough](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 10:58:19 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Shortness of breath](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 10:58:19 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Difficulty breathing](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 10:58:19 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Fatigue](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 10:58:19 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Muscle aches](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 10:58:19 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Body aches](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 10:58:19 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Headache](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 10:58:19 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[New loss of taste](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 10:58:19 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[New loss of smell](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 10:58:19 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Sore throat](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 10:58:19 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Congestion](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 10:58:19 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Runny nose](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 10:58:19 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Nausea](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 10:58:19 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Vomiting](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 10:58:19 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Diarrhea](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 10:58:19 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 10:58:19 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 10:58:19 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 10:58:19 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 10:58:19 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 10:58:19 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 20 Nov 2020 01:55:21 |
| Data entry locked. | System | 24 Aug 2020 20:15:12 |
| User entered '07 Nov 2020 00:01' | System | 24 Aug 2020 20:15:12 |

US3362244

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 10:58:19 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 20 Nov 2020 01:55:21 |
| Data entry locked. | System | 24 Aug 2020 20:15:12 |
| User entered '11 Nov 2020 23:59' | System | 24 Aug 2020 20:15:12 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered 'Day 89' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '18 Nov 2020 00:01' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '22 Nov 2020 23:59' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered 'Day 96' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '25 Nov 2020 00:01' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '29 Nov 2020 23:59' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered 'Day 103' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '02 Dec 2020 00:01' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '06 Dec 2020 23:59' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered 'Day 110' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '09 Dec 2020 00:01' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '13 Dec 2020 23:59' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered 'Day 117' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '16 Dec 2020 00:01' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '20 Dec 2020 23:59' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered 'Day 124' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '23 Dec 2020 00:01' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '27 Dec 2020 23:59' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered 'Day 131' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '30 Dec 2020 00:01' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '03 Jan 2021 23:59' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered 'Day 138' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '06 Jan 2021 00:01' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '10 Jan 2021 23:59' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered 'Day 145' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[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 (82cbad1a1791eaaf)', Time: '2021-01-14T08:54:52', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '22fea40d-9355-43f3-81c4-7136543df9b0' | System | 14 Jan 2021 14:55:25 |
| User entered 'No (N)' | System | 14 Jan 2021 14:55:25 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

Have you been exposed to someone with 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 (82cbad1a1791eaaf)', Time: '2021-01-14T08:55:02', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '22fea40d-9355-43f3-81c4-7136543df9b0' | System | 14 Jan 2021 14:55:25 |
| User entered 'No (N)' | System | 14 Jan 2021 14:55:25 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaaf)', Time: '2021-01-14T08:55:20', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '22fea40d-9355-43f3-81c4-7136543df9b0' | System | 14 Jan 2021 14:55:25 |
| User entered '14 Jan 2021 08:55:20' | System | 14 Jan 2021 14:55:25 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '13 Jan 2021 00:01' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '17 Jan 2021 23:59' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered 'Day 152' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[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 (82cbad1a1791eaaf)', Time: '2021-01-20T09:11:11', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'cce72bf6-5930-49ae-8df0-edc247d8472b' | System | 20 Jan 2021 15:11:33 |
| User entered 'No (N)' | System | 20 Jan 2021 15:11:33 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Have you been exposed to someone with 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 (82cbad1a1791eaaf)', Time: '2021-01-20T09:11:20', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'cce72bf6-5930-49ae-8df0-edc247d8472b' | System | 20 Jan 2021 15:11:33 |
| User entered 'No (N)' | System | 20 Jan 2021 15:11:33 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2021-01-20T09:11:28', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'cce72bf6-5930-49ae-8df0-edc247d8472b' User entered '20 Jan 2021 09:11:28' | System | 20 Jan 2021 15:11:33 |
| | System | 20 Jan 2021 15:11:33 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '20 Jan 2021 00:01' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '24 Jan 2021 23:59' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered 'Day 159' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[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 (82cbad1a1791eaaf)', Time: '2021-01-27T18:14:45', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '8bccba5c-9f04-40a0-890a-b95eb0ba1e5f' | System | 28 Jan 2021 00:15:13 |
| User entered 'No (N)' | System | 28 Jan 2021 00:15:13 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

Have you been exposed to someone with 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 (82cbad1a1791eaaaf)', Time: '2021-01-27T18:14:55', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '8bccba5c-9f04-40a0-890a-b95eb0ba1e5f' | System | 28 Jan 2021 00:15:13 |
| User entered 'No (N)' | System | 28 Jan 2021 00:15:13 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2021-01-27T18:15:08', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '8bccba5c-9f04-40a0-890a-b95eb0ba1e5f' User entered '27 Jan 2021 18:15:08' | System | 28 Jan 2021 00:15:13 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '27 Jan 2021 00:01' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '31 Jan 2021 23:59' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered 'Day 166' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[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 (82cbad1a1791eaf)', Time: '2021-02-05T08:53:14', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '33075cc1-4a4a-4c5b-9fe7-a744aef4a48a' | System | 05 Feb 2021 14:53:32 |
| User entered 'No (N)' | System | 05 Feb 2021 14:53:32 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

Have you been exposed to someone with 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 (82cbad1a1791eaaf)', Time: '2021-02-05T08:53:20', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '33075cc1-4a4a-4c5b-9fe7-a744aef4a48a' | System | 05 Feb 2021 14:53:32 |
| User entered 'No (N)' | System | 05 Feb 2021 14:53:32 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2021-02-05T08:53:29', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '33075cc1-4a4a-4c5b-9fe7-a744aef4a48a' | System | 05 Feb 2021 14:53:32 |
| User entered '05 Feb 2021 08:53:29' | System | 05 Feb 2021 14:53:32 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '03 Feb 2021 00:01' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '07 Feb 2021 23:59' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered 'Day 173' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[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 (82cbad1a1791eaaf)', Time: '2021-02-10T11:50:39', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '015f4961-fee6-475a-bd60-76286074eb45' | System | 10 Feb 2021 17:50:58 |
| User entered 'No (N)' | System | 10 Feb 2021 17:50:58 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

Have you been exposed to someone with 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 (82cbad1a1791eaaf)', Time: '2021-02-10T11:50:43', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '015f4961-fee6-475a-bd60-76286074eb45' | System | 10 Feb 2021 17:50:58 |
| User entered 'No (N)' | System | 10 Feb 2021 17:50:58 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaf)', Time: '2021-02-10T11:50:53', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '015f4961-fee6-475a-bd60-76286074eb45' User entered '10 Feb 2021 11:50:53' | System | 10 Feb 2021 17:50:58 |
| | System | 10 Feb 2021 17:50:58 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '10 Feb 2021 00:01' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '14 Feb 2021 23:59' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered 'Day 180' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[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 (82cbad1a1791eaaf)', Time: '2021-02-17T16:35:02', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'e7a8e4e9-0ddb-49b0-8884-568af34b9b87' | System | 17 Feb 2021 22:35:23 |
| User entered 'No (N)' | System | 17 Feb 2021 22:35:23 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

Have you been exposed to someone with 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 (82cbad1a1791eaaf)', Time: '2021-02-17T16:35:13', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'e7a8e4e9-0ddb-49b0-8884-568af34b9b87' | System | 17 Feb 2021 22:35:23 |
| User entered 'No (N)' | System | 17 Feb 2021 22:35:23 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2021-02-17T16:35:20', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'e7a8e4e9-0ddb-49b0-8884-568af34b9b87' | System | 17 Feb 2021 22:35:23 |
| User entered '17 Feb 2021 16:35:20' | System | 17 Feb 2021 22:35:23 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '17 Feb 2021 00:01' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '21 Feb 2021 23:59' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered 'Day 187' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[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 (82cbad1a1791eaaf)', Time: '2021-02-24T01:09:22-06:00', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'a382fdb1-1862-43ec-9fa0-e90fe6bc0638' User entered 'No (N)' | System | 24 Feb 2021 07:09:52 |
| | System | 24 Feb 2021 07:09:52 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

Have you been exposed to someone with 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 (82cbad1a1791eaaf)', Time: '2021-02-24T01:09:32-06:00', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'a382fdb1-1862-43ec-9fa0-e90fe6bc0638' | System | 24 Feb 2021 07:09:52 |
| User entered 'No (N)' | System | 24 Feb 2021 07:09:52 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaaf)', Time: '2021-02-24T01:09:48-06:00', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'a382fdb1-1862-43ec-9fa0-e90fe6bc0638' User entered '24 Feb 2021 01:09:48' | System | 24 Feb 2021 07:09:52 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '24 Feb 2021 00:01' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '28 Feb 2021 23:59' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered 'Day 194' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '03 Mar 2021 00:01' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '07 Mar 2021 23:59' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered 'Day 201' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[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 (82cbad1a1791eaaf)', Time: '2021-03-10T02:13:34-06:00', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '293ce0f2-3528-470d-b629-8a9db94dfa7b' | System | 10 Mar 2021 08:14:08 |
| User entered 'No (N)' | System | 10 Mar 2021 08:14:08 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

Have you been exposed to someone with 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 (82cbad1a1791eaaf)', Time: '2021-03-10T02:13:54-06:00', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '293ce0f2-3528-470d-b629-8a9db94dfa7b' | System | 10 Mar 2021 08:14:08 |
| User entered 'No (N)' | System | 10 Mar 2021 08:14:08 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2021-03-10T02:14:03-06:00', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '293ce0f2-3528-470d-b629-8a9db94dfa7b' User entered '10 Mar 2021 02:14:03' | System | 10 Mar 2021 08:14:08 |
| | System | 10 Mar 2021 08:14:08 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '10 Mar 2021 00:01' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '14 Mar 2021 23:59' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered 'Day 208' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[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 (82cbad1a1791eaaf)', Time: '2021-03-17T19:36:14-05:00', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '386dbc10-6e6b-4b6f-8247-4d16e690154d' | System | 18 Mar 2021 00:36:40 |
| User entered 'No (N)' | System | 18 Mar 2021 00:36:40 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

Have you been exposed to someone with 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 (82cbad1a1791eaaf)', Time: '2021-03-17T19:36:27-05:00', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '386dbc10-6e6b-4b6f-8247-4d16e690154d' User entered 'No (N)' | System | 18 Mar 2021 00:36:40 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2021-03-17T19:36:37-05:00', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '386dbc10-6e6b-4b6f-8247-4d16e690154d' User entered '17 Mar 2021 19:36:37' | System | 18 Mar 2021 00:36:40 |
| | System | 18 Mar 2021 00:36:40 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '17 Mar 2021 00:01' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '21 Mar 2021 23:59' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered 'Day 215' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '24 Mar 2021 00:01' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '28 Mar 2021 23:59' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered 'Day 222' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '31 Mar 2021 00:01' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '04 Apr 2021 23:59' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered 'Day 229' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '07 Apr 2021 00:01' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '11 Apr 2021 23:59' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered 'Day 236' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '14 Apr 2021 00:01' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '18 Apr 2021 23:59' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered 'Day 243' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '21 Apr 2021 00:01' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '25 Apr 2021 23:59' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered 'Day 250' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[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 (78364848abf6b8d5)', Time: '2021-04-29T13:24:49-05:00', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'a336e033-83c8-45fe-a6a2-130214821d90' User entered 'No (N)' | System | 29 Apr 2021 18:25:31 |
| | System | 29 Apr 2021 18:25:31 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Have you been exposed to someone with 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 (78364848abf6b8d5)', Time: '2021-04-29T13:24:55-05:00', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'a336e033-83c8-45fe-a6a2-130214821d90' | System | 29 Apr 2021 18:25:31 |
| User entered 'No (N)' | System | 29 Apr 2021 18:25:31 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (78364848abf6b8d5)', Time: '2021-04-29T13:25:27-05:00', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: 'a336e033-83c8-45fe-a6a2-130214821d90' User entered '29 Apr 2021 13:25:27' | System | 29 Apr 2021 18:25:31 |
| | System | 29 Apr 2021 18:25:31 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '28 Apr 2021 00:01' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '02 May 2021 23:59' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered 'Day 257' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '05 May 2021 00:01' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '09 May 2021 23:59' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered 'Day 264' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '12 May 2021 00:01' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '16 May 2021 23:59' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered 'Day 271' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '19 May 2021 00:01' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '23 May 2021 23:59' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered 'Day 278' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '26 May 2021 00:01' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '30 May 2021 23:59' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered 'Day 285' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '02 Jun 2021 00:01' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '06 Jun 2021 23:59' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered 'Day 292' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '09 Jun 2021 00:01' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '13 Jun 2021 23:59' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered 'Day 299' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '16 Jun 2021 00:01' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '20 Jun 2021 23:59' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered 'Day 306' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '23 Jun 2021 00:01' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '27 Jun 2021 23:59' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered 'Day 313' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '30 Jun 2021 00:01' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '04 Jul 2021 23:59' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered 'Day 320' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '07 Jul 2021 00:01' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '11 Jul 2021 23:59' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered 'Day 327' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '14 Jul 2021 00:01' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '18 Jul 2021 23:59' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered 'Day 334' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '21 Jul 2021 00:01' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '25 Jul 2021 23:59' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered 'Day 341' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '28 Jul 2021 00:01' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '01 Aug 2021 23:59' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered 'Day 348' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '04 Aug 2021 00:01' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '08 Aug 2021 23:59' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered 'Day 355' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '11 Aug 2021 00:01' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '15 Aug 2021 23:59' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered 'Day 362' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '18 Aug 2021 00:01' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '22 Aug 2021 23:59' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered 'Day 369' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '25 Aug 2021 00:01' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '29 Aug 2021 23:59' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered 'Day 376' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '01 Sep 2021 00:01' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '05 Sep 2021 23:59' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered 'Day 383' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '08 Sep 2021 00:01' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '12 Sep 2021 23:59' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered 'Day 390' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '15 Sep 2021 00:01' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '19 Sep 2021 23:59' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered 'Day 397' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '22 Sep 2021 00:01' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '26 Sep 2021 23:59' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered 'Day 404' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '29 Sep 2021 00:01' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '03 Oct 2021 23:59' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered 'Day 411' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '06 Oct 2021 00:01' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '10 Oct 2021 23:59' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered 'Day 418' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '13 Oct 2021 00:01' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '17 Oct 2021 23:59' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered 'Day 425' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '20 Oct 2021 00:01' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '24 Oct 2021 23:59' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered 'Day 432' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '27 Oct 2021 00:01' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '31 Oct 2021 23:59' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered 'Day 439' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '03 Nov 2021 00:01' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '07 Nov 2021 23:59' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered 'Day 446' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '10 Nov 2021 00:01' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '14 Nov 2021 23:59' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered 'Day 453' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '17 Nov 2021 00:01' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '21 Nov 2021 23:59' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered 'Day 460' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '24 Nov 2021 00:01' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '28 Nov 2021 23:59' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered 'Day 467' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '01 Dec 2021 00:01' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '05 Dec 2021 23:59' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered 'Day 474' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '08 Dec 2021 00:01' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '12 Dec 2021 23:59' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered 'Day 481' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '15 Dec 2021 00:01' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '19 Dec 2021 23:59' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered 'Day 488' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '22 Dec 2021 00:01' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '26 Dec 2021 23:59' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered 'Day 495' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '29 Dec 2021 00:01' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '02 Jan 2022 23:59' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered 'Day 502' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '05 Jan 2022 00:01' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '09 Jan 2022 23:59' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered 'Day 509' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '12 Jan 2022 00:01' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '16 Jan 2022 23:59' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered 'Day 516' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '19 Jan 2022 00:01' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '23 Jan 2022 23:59' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered 'Day 523' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '26 Jan 2022 00:01' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '30 Jan 2022 23:59' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered 'Day 530' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '02 Feb 2022 00:01' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '06 Feb 2022 23:59' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered 'Day 537' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '09 Feb 2022 00:01' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '13 Feb 2022 23:59' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered 'Day 544' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '16 Feb 2022 00:01' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '20 Feb 2022 23:59' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered 'Day 551' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '23 Feb 2022 00:01' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '27 Feb 2022 23:59' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered 'Day 558' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '02 Mar 2022 00:01' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '06 Mar 2022 23:59' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered 'Day 565' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '09 Mar 2022 00:01' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '13 Mar 2022 23:59' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered 'Day 572' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '16 Mar 2022 00:01' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '20 Mar 2022 23:59' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered 'Day 579' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '23 Mar 2022 00:01' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '27 Mar 2022 23:59' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered 'Day 586' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '30 Mar 2022 00:01' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '03 Apr 2022 23:59' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered 'Day 593' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '06 Apr 2022 00:01' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '10 Apr 2022 23:59' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered 'Day 600' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '13 Apr 2022 00:01' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '17 Apr 2022 23:59' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered 'Day 607' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '20 Apr 2022 00:01' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '24 Apr 2022 23:59' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered 'Day 614' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '27 Apr 2022 00:01' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '01 May 2022 23:59' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered 'Day 621' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '04 May 2022 00:01' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '08 May 2022 23:59' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered 'Day 628' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '11 May 2022 00:01' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '15 May 2022 23:59' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered 'Day 635' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '18 May 2022 00:01' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '22 May 2022 23:59' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered 'Day 642' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '25 May 2022 00:01' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '29 May 2022 23:59' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered 'Day 649' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '01 Jun 2022 00:01' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '05 Jun 2022 23:59' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered 'Day 656' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '08 Jun 2022 00:01' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '12 Jun 2022 23:59' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered 'Day 663' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '15 Jun 2022 00:01' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '19 Jun 2022 23:59' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered 'Day 670' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '22 Jun 2022 00:01' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '26 Jun 2022 23:59' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered 'Day 677' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '29 Jun 2022 00:01' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '03 Jul 2022 23:59' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered 'Day 684' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '06 Jul 2022 00:01' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '10 Jul 2022 23:59' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered 'Day 691' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '13 Jul 2022 00:01' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '17 Jul 2022 23:59' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered 'Day 698' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '20 Jul 2022 00:01' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '24 Jul 2022 23:59' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered 'Day 705' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '27 Jul 2022 00:01' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '31 Jul 2022 23:59' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered 'Day 712' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '03 Aug 2022 00:01' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '07 Aug 2022 23:59' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered 'Day 719' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '10 Aug 2022 00:01' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '14 Aug 2022 23:59' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered 'Day 726' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '17 Aug 2022 00:01' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '21 Aug 2022 23:59' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered 'Day 733' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '24 Aug 2022 00:01' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '28 Aug 2022 23:59' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered 'Day 740' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '31 Aug 2022 00:01' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '04 Sep 2022 23:59' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered 'Day 747' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '07 Sep 2022 00:01' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '11 Sep 2022 23:59' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered 'Day 754' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '14 Sep 2022 00:01' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '18 Sep 2022 23:59' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered 'Day 761' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '21 Sep 2022 00:01' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '25 Sep 2022 23:59' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered 'Day 768' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '28 Sep 2022 00:01' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '02 Oct 2022 23:59' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered 'Day 775' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '05 Oct 2022 00:01' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '09 Oct 2022 23:59' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered 'Day 782' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '12 Oct 2022 00:01' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '16 Oct 2022 23:59' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered 'Day 789' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '19 Oct 2022 00:01' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '23 Oct 2022 23:59' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered 'Day 796' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '26 Oct 2022 00:01' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:58

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 01:55:21 |
| Amendment Manager: User entered '30 Oct 2022 23:59' | System | 20 Nov 2020 01:55:21 |

US3362244

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:14:58

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 10:58:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2021-03-09T06:41:35-06:00', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '24575d01-a5e8-4654-a188-8e918081af95' | System | 09 Mar 2021 12:42:02 |
| User entered 'No (N)' | System | 09 Mar 2021 12:42:02 |

US3362244

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:14:58

[Date & Time of Submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 10:58:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (82cbad1a1791eaaf)', Time: '2021-03-09T06:41:46-06:00', User OID: 'PatientReportedOutcome (US3362244)', ODM File OID: '24575d01-a5e8-4654-a188-8e918081af95' User entered '09 Mar 2021 06:41:46' | System | 09 Mar 2021 12:42:02 |
| | System | 09 Mar 2021 12:42:02 |

US3362244

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:58

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 06 Mar 2021 04:26:37 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 19 Nov 2020 22:20:57 |

US3362244

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:58

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 06 Mar 2021 04:26:37 |
| User entered '19 Nov 2020' | (b) (4), (b) (6) | 19 Nov 2020 22:20:57 |

US3362244

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:58

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 06 Mar 2021 04:26:37 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) (b) (4), (b) (6) | 19 Nov 2020 22:20:57 |

US3362244

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:58

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 06 Mar 2021 04:26:37 |
| User entered empty. | (b) (4), (b) (6) | 19 Nov 2020 22:20:57 |

US3362244

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:14:58

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User signature succeeded. | Jordan Whatley (b) (4) | 06 Mar 2021 04:26:37 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 19 Nov 2020 22:21:04 |

US3362244

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:14:58

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 19:46:08 |
| User entered 'I' | System | 19 Nov 2020 22:21:04 |

US3362244

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:58

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:04:42 |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 14 Jan 2021 14:51:27 |

US3362244

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:58

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:04:42 |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| User entered '22 Dec 2020' | (b) (4) (b) (4), (b) (6) | 14 Jan 2021 14:51:27 |

US3362244

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:58

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:04:42 |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) (b) (4), (b) (6) | 14 Jan 2021 14:51:27 |

US3362244

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:58

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:04:42 |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 14 Jan 2021 14:51:27 |

US3362244

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:14:58

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:04:42 |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 14 Jan 2021 14:51:33 |

US3362244

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:14:58

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:04:42 |
| User entered 'I' | System | 14 Jan 2021 14:51:33 |

US3362244

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:58

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:04:42 |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| User entered 'Yes (Y)' | Alexandra Caillouet (b) (4) | 03 Feb 2021 17:33:48 |

US3362244

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:58

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:04:42 |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| User entered '18 Jan 2021' | Alexandra Caillouet (b) (4) | 03 Feb 2021 17:33:48 |

US3362244

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:58

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:04:42 |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| User entered 'Contact Made (CONTACT MADE)' | Alexandra Caillouet (b) (4) | 03 Feb 2021 17:33:48 |

US3362244

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:58

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:04:42 |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| User entered empty. | Alexandra Caillouet (b) (4) | 03 Feb 2021 17:33:48 |

US3362244

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:14:58

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:04:42 |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| User entered 'Yes (Y)' | Alexandra Caillouet (b) (4) | 03 Feb 2021 17:33:55 |

US3362244

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:14:58

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:04:42 |
| User entered 'I' | System | 03 Feb 2021 17:33:55 |

US3362244

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:58

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:04:42 |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 18 Feb 2021 22:33:50 |

US3362244

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:58

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:04:42 |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| User entered '18 Feb 2021' | (b) (4), (b) (6) | 18 Feb 2021 22:33:50 |

US3362244

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:58

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:04:42 |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4), (b) (6) | 18 Feb 2021 22:33:50 |

US3362244

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:58

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:04:42 |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| User entered empty. | (b) (4), (b) (6) | 18 Feb 2021 22:33:50 |

US3362244

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:14:58

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:04:42 |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 18 Feb 2021 22:33:54 |

US3362244

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:14:58

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 03:04:42 |
| User entered 'I' | System | 18 Feb 2021 22:33:54 |

US3362244

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:14:58

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 09:08:59 |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| User entered 'Yes (Y)' | Alexandra Caillouet (b) (4) | 10 Mar 2021 17:54:37 |

US3362244

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 09:08:59 |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| User entered '10 Mar 2021' | Alexandra Caillouet (b) (4) | 10 Mar 2021 17:54:37 |

US3362244

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 09:08:59 |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| User entered 'Clinic (Clinic)' | Alexandra Caillouet (b) (4) | 10 Mar 2021 17:54:37 |

US3362244

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:14:58

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 09:08:59 |
| User entered 'VISIT4' | System | 10 Mar 2021 17:54:37 |

US3362244

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:14:58

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 09:08:59 |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| User entered 'No (N)' | Alexandra Caillouet (b) (4) | 10 Mar 2021 17:54:44 |

US3362244

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:14:58

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 09:08:59 |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| User entered empty. | Alexandra Caillouet (b) (4) | 10 Mar 2021 17:54:44 |

US3362244

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:14:58

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 09:08:59 |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| User entered 'Yes (Y)' | Alexandra Caillouet (b) (4) | 10 Mar 2021 17:55:01 |

US3362244

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:14:58

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 09:08:59 |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| User entered '10 Mar 2021' | Alexandra Caillouet (b) (4) | 10 Mar 2021 17:55:01 |

US3362244

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:14:58

[Collection time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 09:08:59 |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| User entered '10:43' | Alexandra Caillouet (b) (4) | 10 Mar 2021 17:55:01 |

US3362244

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 09:08:59 |
| User entered '10 Mar 2021 10:43' | System | 10 Mar 2021 17:55:01 |

US3362244

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:14:58

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 09:08:59 |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| User entered 'Yes (Y)' | Alexandra Caillouet (b) (4) | 10 Mar 2021 17:55:07 |

US3362244

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:14:58

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 09:08:59 |
| User entered 'I' | System | 10 Mar 2021 17:55:07 |

US3362244

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:58

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 21 Apr 2021 15:40:18 |

US3362244

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:58

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| User entered '21 Apr 2021' | (b) (4) (b) (4), (b) (6) | 21 Apr 2021 15:40:18 |

US3362244

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:58

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) (b) (4), (b) (6) | 21 Apr 2021 15:40:18 |

US3362244

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:58

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Apr 2021 15:40:18 |

US3362244

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:14:58

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 21 Apr 2021 15:40:23 |

US3362244

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:14:58

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 21 Apr 2021 15:40:23 |

US3362244

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

Form: Visit Date

Generated On: 09 Jun 2021 17:14:58

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:00:26 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| | (b) (4) | |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 06 Jan 2021 22:20:04 |
| | | |

US3362244

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

Form: Visit Date

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:00:26 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| | (b) (4) | |
| User entered '6 Jan 2021' | (b) (4), (b) (6) | 06 Jan 2021 22:20:04 |
| | | |

US3362244

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

Form: Visit Date

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|--------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:00:26 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| | (b) (4) | |
| User entered 'Clinic (Clinic)' | (b) (4), (b) (6) | 06 Jan 2021 22:20:04 |
| | | |

US3362244

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

Form: Visit Date

Generated On: 09 Jun 2021 17:14:58

[Folder OID](#)

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:00:26 |
| | | |
| User entered 'UNBLND_DECIDE' | System | 06 Jan 2021 22:20:04 |

US3362244

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

Form: Unblinding

Generated On: 09 Jun 2021 17:14:58

Date of updated informed consent (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:00:26 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| | (b) (4) | |
| User entered '06 Jan 2021' reason for change: Data Entry Error | Amy Thomassie (b) (4) | 18 Feb 2021 21:07:52 |
| | (b) (4) | |
| User entered '24 Dec 2020' | (b) (4), (b) (6) | 06 Jan 2021 22:21:13 |
| | | |

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

Form: Unblinding

Generated On: 09 Jun 2021 17:14:58

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:00:26 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| | (b) (4) | |
| User entered '0' WR# 5295537 | System | 10 Mar 2021 16:55:28 |
| Amendment Manager inserted this DataPoint. | System | 06 Mar 2021 13:49:49 |

US3362244

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

Form: Unblinding

Generated On: 09 Jun 2021 17:14:58

[Was the participant unblinded?](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:00:26 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| | (b) (4) | |
| User closed query 'Was the participant unblinded is Yes however, data is missing. Please reconcile.' (Site from System). | (b) (4), (b) (6) | 07 Jan 2021 18:56:02 |
| | | |
| Query 'Was the participant unblinded is Yes however, data is missing. Please reconcile.' answered with 'participant did not receive an Actual Dose 2' (Site from System). | (b) (4), (b) (6) | 06 Jan 2021 22:22:03 |
| | | |
| User opened query 'Was the participant unblinded is Yes however, data is missing. Please reconcile.' (Site from System). | System | 06 Jan 2021 22:21:13 |
| | | |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 06 Jan 2021 22:21:13 |
| | | |

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

Form: Unblinding

Generated On: 09 Jun 2021 17:14:58

[Under what version of the Protocol was the Participant unblinded?](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:00:26 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| | (b) (4) | |
| User entered 'Amendment 6 or later (Amendment 6 or later)' reason for change: Data Entry Error | Alexandra Caillouet | 10 Mar 2021 17:53:50 |
| | (b) (4) | |
| User entered 'AMENDMENT 5 (AMENDMENT 5)' | System | 10 Mar 2021 16:55:28 |
| WR# 5295537 | | |
| Amendment Manager inserted this DataPoint. | System | 06 Mar 2021 13:49:49 |

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

Form: Unblinding

Generated On: 09 Jun 2021 17:14:58

Date of unblinding (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:00:26 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| | (b) (4) | |
| User closed query 'Per CDM: Please clarify the reason why updated informed consent was signed much earlier than actual visit and unblinding took place. Thank you! | (b) (4), (b) (6) | 19 Feb 2021 17:35:34 |
| ' (Site from DM). | | |
| Query 'Per CDM: Please clarify the reason why updated informed consent was signed much earlier than actual visit and unblinding took place. Thank you! | Amy Thomassie (b) (4) | 18 Feb 2021 21:07:56 |
| | (b) (4) | |
| ' answered with 'updated ICF date' (Site from DM). | | |
| User opened query 'Per CDM: Please clarify the reason why updated informed consent was signed much earlier than actual visit and unblinding took place. Thank you! | (b) (4), (b) (6) | 18 Feb 2021 10:57:55 |
| | | |
| ' (Site from DM). | | |
| User entered '6 Jan 2021' | (b) (4), (b) (6) | 06 Jan 2021 22:21:13 |
| | | |

US3362244

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

Form: Unblinding

Generated On: 09 Jun 2021 17:14:58

[Participant randomization assignment](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:00:26 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| | (b) (4) | |
| User entered 'mRNA-1273 (mRNA-1273)' reason for change: Data Entry Error | Alexandra Caillouet | 08 Feb 2021 23:26:09 |
| | (b) (4) | |
| User entered 'Placebo (Placebo)' | (b) (4), (b) (6) | 06 Jan 2021 22:21:13 |
| | | |

US3362244

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

Form: Unblinding

Generated On: 09 Jun 2021 17:14:58

[Actual Dose 1](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:00:26 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| | (b) (4) | |
| User entered 'mRNA-1273 (mRNA-1273)' reason for change: Data Entry Error | Alexandra Caillouet | 08 Feb 2021 23:26:09 |
| | (b) (4) | |
| Amendment Manager: User entered 'Placebo (Placebo)' | System | 20 Jan 2021 08:17:45 |
| User entered 'Placebo (Placebo)' | (b) (4), (b) (6) | 06 Jan 2021 22:21:13 |
| | | |

US3362244

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

Form: Unblinding

Generated On: 09 Jun 2021 17:14:58

[Actual Dose 2](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:00:26 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| | (b) (4) | |
| User entered 'Not Administered (NA)' reason for change: Data Entry Error | Alexandra Caillouet | 25 Jan 2021 22:53:37 |
| | (b) (4) | |
| User entered empty. | (b) (4), (b) (6) | 06 Jan 2021 22:21:13 |
| | | |

US3362244

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

Form: Unblinding

Generated On: 09 Jun 2021 17:14:58

[Will participant receive mRNA-1273?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:00:26 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| | (b) (4) | |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 06 Jan 2021 22:21:13 |
| | | |

US3362244

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

Form: Unblinding

Generated On: 09 Jun 2021 17:14:58

[Placebo Only Flag](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:00:26 |
| | | |
| User entered empty. | System | 08 Feb 2021 23:26:09 |
| User entered 'I' | System | 25 Jan 2021 22:53:37 |
| User entered empty. | System | 06 Jan 2021 22:21:13 |

US3362244

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

Form: Unblinding

Generated On: 09 Jun 2021 17:14:58

[Continuing with mRNA-1273](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:00:26 |
| | | |
| User entered 'I' | System | 25 Jan 2021 22:53:37 |
| User entered empty. | System | 06 Jan 2021 22:21:13 |

US3362244

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:14:58

[Height](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:00:26 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| | (b) (4) | |
| User entered missing code ND - Not Done. | Alexandra Caillouet | 25 Jan 2021 22:57:17 |
| | (b) (4) | |

US3362244

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:14:58

[Weight](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:00:26 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| | (b) (4) | |
| User entered missing code ND - Not Done. | Alexandra Caillouet | 25 Jan 2021 22:57:17 |
| | (b) (4) | |

US3362244

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:14:58

BMI (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:00:26 |
| | | |
| User entered empty. | System | 25 Jan 2021 22:57:17 |
| DataPoint set to visible. | System | 25 Jan 2021 22:53:37 |

US3362244

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:14:58

[Height](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:00:26 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| | (b) (4) | |
| User entered missing code ND - Not Done. | Alexandra Caillouet | 25 Jan 2021 22:57:17 |
| | (b) (4) | |

US3362244

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:14:58

[Weight](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:00:26 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| | (b) (4) | |
| User entered missing code ND - Not Done. | Alexandra Caillouet | 25 Jan 2021 22:57:17 |
| | (b) (4) | |

US3362244

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:14:58

BMI (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:00:26 |
| | | |
| User entered empty. | System | 25 Jan 2021 22:57:17 |
| DataPoint set to visible. | System | 25 Jan 2021 22:53:37 |

US3362244

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:58

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:00:26 |
| | | |
| User accepted default value 'Pre-Dose (PREDOSE)' | Alexandra Caillouet | 25 Jan 2021 22:57:17 |
| | (b) (4) | |

US3362244

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:58

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:00:26 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Alexandra Caillouet | 25 Jan 2021 22:57:17 |
| | (b) (4) | |

US3362244

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:58

Date of assessment (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:00:26 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| | (b) (4) | |
| User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System). | System | 25 Jan 2021 22:57:51 |
| User entered '6 Jan 2021' reason for change: Data Entry Error | Alexandra Caillouet (b) (4) | 25 Jan 2021 22:57:51 |
| User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System). | System | 25 Jan 2021 22:57:17 |
| User entered '25 Jan 2021' | Alexandra Caillouet (b) (4) | 25 Jan 2021 22:57:17 |

US3362244

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:00:26 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| | (b) (4) | |
| User entered '07:55' | Alexandra Caillouet | 25 Jan 2021 22:57:17 |
| | (b) (4) | |

US3362244

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:00:26 |
| | | |
| User entered '6 Jan 2021 07:55' | System | 25 Jan 2021 22:57:51 |
| User entered '25 Jan 2021 07:55' | System | 25 Jan 2021 22:57:17 |

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:58

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:00:26 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| | (b) (4) | |
| User entered '36.7' C | Alexandra Caillouet | 25 Jan 2021 22:57:17 |
| | (b) (4) | |

US3362244

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:58

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:00:26 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| | (b) (4) | |
| User entered 'Oral (Oral)' | Alexandra Caillouet | 25 Jan 2021 22:57:17 |
| | (b) (4) | |

US3362244

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:58

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:00:26 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| | (b) (4) | |
| User entered empty. | Alexandra Caillouet | 25 Jan 2021 22:57:17 |
| | (b) (4) | |

US3362244

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:58

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:00:26 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| | (b) (4) | |
| User entered '73' | Alexandra Caillouet | 25 Jan 2021 22:57:17 |
| | (b) (4) | |

US3362244

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:58

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:00:26 |
| | | |
| User entered 'bpm' | System | 25 Jan 2021 22:57:17 |

US3362244

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:00:26 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| | (b) (4) | |
| User entered '12' | Alexandra Caillouet | 25 Jan 2021 22:57:17 |
| | (b) (4) | |

US3362244

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:58

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:00:26 |
| | | |
| User entered 'breaths/min' | System | 25 Jan 2021 22:57:17 |

US3362244

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:58

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:00:26 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| | (b) (4) | |
| User entered '122' | Alexandra Caillouet | 25 Jan 2021 22:57:17 |
| | (b) (4) | |

US3362244

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:58

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:00:26 |
| | | |
| User entered 'mmHg' | System | 25 Jan 2021 22:57:17 |

US3362244

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:58

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:00:26 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| | (b) (4) | |
| User entered '78' | Alexandra Caillouet | 25 Jan 2021 22:57:17 |
| | (b) (4) | |

US3362244

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:58

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:00:26 |
| | | |
| User entered 'mmHg' | System | 25 Jan 2021 22:57:17 |

US3362244

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:14:58

[Height](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:00:26 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| | (b) (4) | |
| User entered missing code ND - Not Done. | Alexandra Caillouet | 25 Jan 2021 22:57:17 |
| | (b) (4) | |

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:14:58

[Weight](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:00:26 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| | (b) (4) | |
| User entered missing code ND - Not Done. | Alexandra Caillouet | 25 Jan 2021 22:57:17 |
| | (b) (4) | |

US3362244

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:14:58

BMI (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:00:26 |
| | | |
| User entered empty. | System | 25 Jan 2021 22:57:17 |
| DataPoint set to visible. | System | 25 Jan 2021 22:53:37 |

US3362244

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:58

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:00:26 |
| | | |
| User accepted default value 'Post-Dose (POSTDOSE)' | Alexandra Caillouet (b) (4) | 25 Jan 2021 22:57:17 |

US3362244

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:58

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:00:26 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Alexandra Caillouet | 25 Jan 2021 22:57:17 |
| | (b) (4) | |

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:58

Date of assessment (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:00:26 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| | (b) (4) | |
| User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System). | System | 25 Jan 2021 22:58:01 |
| User entered '6 Jan 2021' reason for change: Data Entry Error | Alexandra Caillouet (b) (4) | 25 Jan 2021 22:58:01 |
| User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System). | System | 25 Jan 2021 22:57:17 |
| User entered '25 Jan 2021' | Alexandra Caillouet (b) (4) | 25 Jan 2021 22:57:17 |

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:00:26 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| | (b) (4) | |
| User entered '08:55' | Alexandra Caillouet | 25 Jan 2021 22:57:17 |
| | (b) (4) | |

US3362244

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:00:26 |
| | | |
| User entered '6 Jan 2021 08:55' | System | 25 Jan 2021 22:58:01 |
| User entered '25 Jan 2021 08:55' | System | 25 Jan 2021 22:57:17 |

US3362244

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:58

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:00:26 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| | (b) (4) | |
| User entered '36.8' C | Alexandra Caillouet | 25 Jan 2021 22:57:17 |
| | (b) (4) | |

US3362244

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:58

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:00:26 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| | (b) (4) | |
| User entered 'Oral (Oral)' | Alexandra Caillouet | 25 Jan 2021 22:57:17 |
| | (b) (4) | |

US3362244

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:58

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:00:26 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| | (b) (4) | |
| User entered empty. | Alexandra Caillouet | 25 Jan 2021 22:57:17 |
| | (b) (4) | |

US3362244

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:58

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:00:26 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| | (b) (4) | |
| User entered '67' | Alexandra Caillouet | 25 Jan 2021 22:57:17 |
| | (b) (4) | |

US3362244

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:58

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:00:26 |
| | | |
| User entered 'bpm' | System | 25 Jan 2021 22:57:17 |

US3362244

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:00:26 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| | (b) (4) | |
| User entered '16' | Alexandra Caillouet | 25 Jan 2021 22:57:17 |
| | (b) (4) | |

US3362244

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:58

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:00:26 |
| | | |
| User entered 'breaths/min' | System | 25 Jan 2021 22:57:17 |

US3362244

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:58

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:00:26 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| | (b) (4) | |
| User entered '133' | Alexandra Caillouet | 25 Jan 2021 22:57:17 |
| | (b) (4) | |

US3362244

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:58

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:00:26 |
| | | |
| User entered 'mmHg' | System | 25 Jan 2021 22:57:17 |

US3362244

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:58

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:00:26 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| | (b) (4) | |
| User entered '85' | Alexandra Caillouet | 25 Jan 2021 22:57:17 |
| | (b) (4) | |

US3362244

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:58

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:00:26 |
| | | |
| User entered 'mmHg' | System | 25 Jan 2021 22:57:17 |

US3362244

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

Form: Physical Examination

Generated On: 09 Jun 2021 17:14:58

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:00:26 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Alexandra Caillouet | 25 Jan 2021 22:58:11 |
| | (b) (4) | |

US3362244

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

Form: Physical Examination

Generated On: 09 Jun 2021 17:14:58

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:00:26 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| | (b) (4) | |
| User entered '6 Jan 2021' | Alexandra Caillouet | 25 Jan 2021 22:58:11 |
| | (b) (4) | |

US3362244

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

Form: Exposure

Generated On: 09 Jun 2021 17:14:58

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:00:26 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Alexandra Caillouet | 25 Jan 2021 22:58:30 |
| | (b) (4) | |

US3362244

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

Form: Exposure

Generated On: 09 Jun 2021 17:14:58

[If No, reason not given](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:00:26 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| | (b) (4) | |
| User entered empty. | Alexandra Caillouet | 25 Jan 2021 22:58:30 |
| | (b) (4) | |

US3362244

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

Form: Exposure

Generated On: 09 Jun 2021 17:14:58

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 Apr 2021 16:00:26 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| | (b) (4) | |
| User entered empty. | Alexandra Caillouet | 25 Jan 2021 22:58:30 |
| | (b) (4) | |

US3362244

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

Form: Exposure

Generated On: 09 Jun 2021 17:14:58

[What was the study treatment? \(Unblinded\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:00:26 |
| | | |
| User entered 'mRNA-1273' | System | 25 Jan 2021 22:58:30 |
| DataPoint set to visible. | System | 25 Jan 2021 22:53:37 |

US3362244

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

Form: Exposure

Generated On: 09 Jun 2021 17:14:58

What was the treatment date? (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:00:26 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| | (b) (4) | |
| User entered '6 Jan 2021' | Alexandra Caillouet | 25 Jan 2021 22:58:30 |
| | (b) (4) | |

US3362244

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

Form: Exposure

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:00:26 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| | (b) (4) | |
| User entered '08:19' | Alexandra Caillouet | 25 Jan 2021 22:58:30 |
| | (b) (4) | |

US3362244

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

Form: Exposure

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:00:26 |
| | | |
| User entered '6 Jan 2021 08:19' | System | 25 Jan 2021 22:58:30 |

US3362244

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

Form: Exposure

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|------------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:00:26 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| | (b) (4) | |
| User entered 'Left Arm (LEFT ARM)' | Alexandra Caillouet | 25 Jan 2021 22:58:30 |
| | (b) (4) | |

US3362244

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

Form: Exposure

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:00:26 |
| | | |
| User entered 'ONCE' | System | 25 Jan 2021 22:58:30 |

US3362244

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

Form: Exposure

Generated On: 09 Jun 2021 17:14:58

What was the route of administration for the study treatment?

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:00:26 |
| | | |
| User entered 'INTRAMUSCULAR' | System | 25 Jan 2021 22:58:30 |

US3362244

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:14:58

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:00:26 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| | (b) (4) | |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 06 Jan 2021 22:24:05 |
| | | |

US3362244

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:14:58

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:00:26 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| | (b) (4) | |
| User entered '6 Jan 2021' | (b) (4), (b) (6) | 06 Jan 2021 22:24:05 |
| | | |

US3362244

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:14:58

[Collection time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:00:26 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| | (b) (4) | |
| User entered '07:44' | (b) (4), (b) (6) | 06 Jan 2021 22:24:05 |
| | | |

US3362244

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:00:26 |
| | | |
| User entered '6 Jan 2021 07:44' | System | 06 Jan 2021 22:24:05 |

US3362244

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:14:58

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:00:26 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| | (b) (4) | |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 06 Jan 2021 22:24:21 |
| | | |

US3362244

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:14:58

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:00:26 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| | (b) (4) | |
| User entered '6 Jan 2021' | (b) (4), (b) (6) | 06 Jan 2021 22:24:21 |
| | | |

US3362244

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:14:58

[Collection time \(00:00 - 23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:00:26 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| | (b) (4) | |
| User entered '07:45' | (b) (4), (b) (6) | 06 Jan 2021 22:24:21 |
| | | |

US3362244

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:00:26 |
| | | |
| User entered '6 Jan 2021 07:45' | System | 06 Jan 2021 22:24:21 |

US3362244

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

Form: Continuing

Generated On: 09 Jun 2021 17:14:58

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:00:26 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Alexandra Caillouet | 25 Jan 2021 22:58:34 |
| | (b) (4) | |

US3362244

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

Form: Continuing

Generated On: 09 Jun 2021 17:14:58

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 16:00:26 |
| | | |
| User entered 'I' | System | 25 Jan 2021 22:58:34 |

US3362244

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:58

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:13:48 |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| User entered 'Yes (Y)' | Alexandra Caillouet (b) (4) | 03 Feb 2021 17:34:23 |

US3362244

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:58

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:13:48 |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| User entered '14 Jan 2021' | Alexandra Caillouet (b) (4) | 03 Feb 2021 17:34:23 |

US3362244

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:58

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:13:48 |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| User entered 'Contact Made (CONTACT MADE)' | Alexandra Caillouet (b) (4) | 03 Feb 2021 17:34:23 |

US3362244

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:58

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:13:48 |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| User entered empty. | Alexandra Caillouet (b) (4) | 03 Feb 2021 17:34:23 |

US3362244

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:14:58

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:13:48 |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| User entered 'Yes (Y)' | Alexandra Caillouet (b) (4) | 03 Feb 2021 17:34:32 |

US3362244

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:14:58

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:13:48 |
| User entered 'I' | System | 03 Feb 2021 17:34:32 |

US3362244

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:14:58

[OLD29 Placebo Flag](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:13:48 |
| User entered '1' | System | 03 Feb 2021 17:34:32 |
| DataPoint set to visible. | System | 03 Feb 2021 17:34:32 |

US3362244

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:14:58

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:32:16 |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| User closed query 'Was this visit performed is Yes, however Visit Date is missing. Please provide.' (Site from System). | (b) (4) | 03 Feb 2021 17:35:01 |
| User opened query 'Was this visit performed is Yes, however Visit Date is missing. Please provide.' (Site from System). | System | 03 Feb 2021 17:34:46 |
| User entered 'Yes (Y)' | Alexandra Caillouet | 03 Feb 2021 17:34:46 |
| | (b) (4) | |

US3362244

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:32:16 |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| User entered '3 Feb 2021' reason for change: Data Entry Error | Alexandra Caillouet (b) (4) | 03 Feb 2021 17:35:01 |
| User entered empty. | Alexandra Caillouet (b) (4) | 03 Feb 2021 17:34:46 |

US3362244

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:32:16 |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| User entered 'Clinic (Clinic)' | Alexandra Caillouet (b) (4) | 03 Feb 2021 17:34:46 |

US3362244

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:14:58

[Folder OID](#)

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:32:16 |
| User entered 'OLD29' | System | 03 Feb 2021 17:34:46 |

US3362244

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:58

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:32:16 |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| User entered 'Yes (Y)' | Alexandra Caillouet (b) (4) | 10 Mar 2021 17:56:29 |

US3362244

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:58

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:32:16 |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| User closed query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System). | (b) (4) | 10 Mar 2021 17:57:26 |
| Query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' answered by data change (Site from System). | System | 10 Mar 2021 17:57:26 |
| User entered '03 Feb 2021' reason for change: Data Entry Error | Alexandra Caillouet (b) (4) | 10 Mar 2021 17:57:26 |
| User opened query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System). | System | 10 Mar 2021 17:56:29 |
| User entered '10 Mar 2021' | Alexandra Caillouet (b) (4) | 10 Mar 2021 17:56:29 |

US3362244

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:32:16 |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| User entered '10:45' | Alexandra Caillouet (b) (4) | 10 Mar 2021 17:56:29 |

US3362244

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:32:16 |
| User entered '03 Feb 2021 10:45' | System | 10 Mar 2021 17:57:26 |
| User entered '10 Mar 2021 10:45' | System | 10 Mar 2021 17:56:29 |

US3362244

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:58

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:32:16 |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| User entered '37.0' C | Alexandra Caillouet (b) (4) | 10 Mar 2021 17:56:29 |

US3362244

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:58

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:32:16 |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| User entered 'Oral (Oral)' | Alexandra Caillouet (b) (4) | 10 Mar 2021 17:56:29 |

US3362244

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:58

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:32:16 |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| User entered empty. | Alexandra Caillouet (b) (4) | 10 Mar 2021 17:56:29 |

US3362244

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:58

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:32:16 |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| User entered '74' | Alexandra Caillouet (b) (4) | 10 Mar 2021 17:56:29 |

US3362244

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:58

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:32:16 |
| User entered 'bpm' | System | 10 Mar 2021 17:56:29 |

US3362244

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:32:16 |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| User entered '18' | Alexandra Caillouet (b) (4) | 10 Mar 2021 17:56:29 |

US3362244

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:58

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:32:16 |
| User entered 'breaths/min' | System | 10 Mar 2021 17:56:29 |

US3362244

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:32:16 |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| User entered '143' | Alexandra Caillouet (b) (4) | 10 Mar 2021 17:56:29 |

US3362244

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:58

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:32:16 |
| User entered 'mmHg' | System | 10 Mar 2021 17:56:29 |

US3362244

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:32:16 |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| User entered '86' | Alexandra Caillouet (b) (4) | 10 Mar 2021 17:56:29 |

US3362244

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:58

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:32:16 |
| User entered 'mmHg' | System | 10 Mar 2021 17:56:29 |

US3362244

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:58

[Height \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:32:16 |
| | | |

US3362244

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:58

[Weight \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:32:16 |
| | | |

US3362244

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:58

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:32:16 |
| User accepted default value 'Pre-Dose (PREDOSE)' | Alexandra Caillouet (b) (4) | 03 Feb 2021 17:36:28 |

US3362244

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:58

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:32:16 |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| User entered 'Yes (Y)' | Alexandra Caillouet (b) (4) | 03 Feb 2021 17:36:28 |

US3362244

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:58

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:32:16 |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| User entered '3 Feb 2021' | Alexandra Caillouet (b) (4) | 03 Feb 2021 17:36:28 |

US3362244

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:32:16 |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| User entered '10:45' | Alexandra Caillouet (b) (4) | 03 Feb 2021 17:36:28 |

US3362244

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:32:16 |
| User entered '3 Feb 2021 10:45' | System | 03 Feb 2021 17:36:28 |

US3362244

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:58

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:32:16 |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| User entered '37.0' C | Alexandra Caillouet (b) (4) | 03 Feb 2021 17:36:28 |

US3362244

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:58

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:32:16 |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| User entered 'Oral (Oral)' | Alexandra Caillouet (b) (4) | 03 Feb 2021 17:36:28 |

US3362244

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:58

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:32:16 |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| User entered empty. | Alexandra Caillouet (b) (4) | 03 Feb 2021 17:36:28 |

US3362244

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:58

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:32:16 |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| User entered '74' | Alexandra Caillouet (b) (4) | 03 Feb 2021 17:36:28 |

US3362244

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:58

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:32:16 |
| User entered 'bpm' | System | 03 Feb 2021 17:36:28 |

US3362244

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:32:16 |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| User entered '18' | Alexandra Caillouet (b) (4) | 03 Feb 2021 17:36:28 |

US3362244

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:58

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:32:16 |
| User entered 'breaths/min' | System | 03 Feb 2021 17:36:28 |

US3362244

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:32:16 |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| User entered '143' | Alexandra Caillouet (b) (4) | 03 Feb 2021 17:36:28 |

US3362244

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:58

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:32:16 |
| User entered 'mmHg' | System | 03 Feb 2021 17:36:28 |

US3362244

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:32:16 |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| User entered '86' | Alexandra Caillouet (b) (4) | 03 Feb 2021 17:36:28 |

US3362244

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:58

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:32:16 |
| User entered 'mmHg' | System | 03 Feb 2021 17:36:28 |

US3362244

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:58

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:32:16 |
| User accepted default value 'Post-Dose (POSTDOSE)' | Alexandra Caillouet (b) (4) | 03 Feb 2021 17:36:28 |

US3362244

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:58

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:32:16 |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| User entered 'No (N)' | Alexandra Caillouet (b) (4) | 03 Feb 2021 17:36:28 |

US3362244

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:58

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:32:16 |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| User entered empty. | Alexandra Caillouet (b) (4) | 03 Feb 2021 17:36:28 |

US3362244

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:32:16 |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| User entered empty. | Alexandra Caillouet (b) (4) | 03 Feb 2021 17:36:28 |

US3362244

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:32:16 |
| User entered empty. | System | 03 Feb 2021 17:36:28 |

US3362244

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:32:16 |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| User entered empty. | Alexandra Caillouet (b) (4) | 03 Feb 2021 17:36:28 |

US3362244

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:58

[Route of measurement](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:32:16 |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| User entered empty. | Alexandra Caillouet (b) (4) | 03 Feb 2021 17:36:28 |

US3362244

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:58

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:32:16 |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| User entered empty. | Alexandra Caillouet (b) (4) | 03 Feb 2021 17:36:28 |

US3362244

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:58

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:32:16 |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| User entered empty. | Alexandra Caillouet (b) (4) | 03 Feb 2021 17:36:28 |

US3362244

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:58

[Pulse units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:32:16 |
| User entered empty. | System | 03 Feb 2021 17:36:28 |

US3362244

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:32:16 |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| User entered empty. | Alexandra Caillouet (b) (4) | 03 Feb 2021 17:36:28 |

US3362244

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:58

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:32:16 |
| User entered empty. | System | 03 Feb 2021 17:36:28 |

US3362244

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:32:16 |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| User entered empty. | Alexandra Caillouet (b) (4) | 03 Feb 2021 17:36:28 |

US3362244

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:58

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:32:16 |
| User entered empty. | System | 03 Feb 2021 17:36:28 |

US3362244

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:32:16 |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| User entered empty. | Alexandra Caillouet (b) (4) | 03 Feb 2021 17:36:28 |

US3362244

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:58

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:32:16 |
| User entered empty. | System | 03 Feb 2021 17:36:28 |

US3362244

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:14:58

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:32:16 |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| User entered 'No (N)' | Alexandra Caillouet (b) (4) | 03 Feb 2021 17:35:23 |

US3362244

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:14:58

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:32:16 |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| User entered empty. | Alexandra Caillouet (b) (4) | 03 Feb 2021 17:35:23 |

US3362244

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:14:58

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:32:16 |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| User entered 'No (N)' | Alexandra Caillouet (b) (4) | 03 Feb 2021 17:39:00 |

US3362244

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:14:58

[If No, reason not given](#)

| Audit | User | Time (GMT) |
|------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:32:16 |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| User entered 'Other (OTHER)' | Alexandra Caillouet (b) (4) | 03 Feb 2021 17:39:00 |

US3362244

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:32:16 |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| User closed query 'Per CDM: Kindly review info recorded at unblinding visit since subject received Dose 1 = Placebo and Dose 2 = Not administered in Part A of study, and then in Part B subject received only one dose of IP. Please update as needed, else provide clarification.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 09 Feb 2021 17:28:40 |
| Query 'Per CDM: Kindly review info recorded at unblinding visit since subject received Dose 1 = Placebo and Dose 2 = Not administered in Part A of study, and then in Part B subject received only one dose of IP. Please update as needed, else provide clarification.' answered with 'Unblinding Visit EDC corrected.' (Site from DM). | Alexandra Caillouet (b) (4) | 08 Feb 2021 23:26:44 |
| User opened query 'Per CDM: Kindly review info recorded at unblinding visit since subject received Dose 1 = Placebo and Dose 2 = Not administered in Part A of study, and then in Part B subject received only one dose of IP. Please update as needed, else provide clarification.' (Site from DM). | (b) (4), (b) (6) | 08 Feb 2021 16:19:57 |
| User entered 'Subject received first dose of mRNA1273 during Phase A and 2nd dose during OL-1 visit.' | Alexandra Caillouet (b) (4) | 03 Feb 2021 17:39:00 |

US3362244

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:14:58

[What was the study treatment?](#)

| Audit | User | Time (GMT) |
|-----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:32:16 |
| DataPoint set to visible. | System | 08 Feb 2021 23:26:09 |
| User entered empty. | System | 03 Feb 2021 17:39:00 |
| DataPoint set to invisible. | System | 03 Feb 2021 17:34:32 |

US3362244

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:14:58

What was the treatment date? (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:32:16 |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| User entered empty. | Alexandra Caillouet (b) (4) | 03 Feb 2021 17:39:00 |

US3362244

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:32:16 |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| User entered empty. | Alexandra Caillouet (b) (4) | 03 Feb 2021 17:39:00 |

US3362244

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:32:16 |
| User entered empty. | System | 03 Feb 2021 17:39:00 |

US3362244

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:32:16 |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| User entered empty. | Alexandra Caillouet (b) (4) | 03 Feb 2021 17:39:00 |

US3362244

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:32:16 |
| User entered empty. | System | 03 Feb 2021 17:39:00 |

US3362244

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:14:58

What was the route of administration for the study treatment?

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:32:16 |
| User entered empty. | System | 03 Feb 2021 17:39:00 |

US3362244

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:14:58

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:32:16 |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| User entered 'Yes (Y)' | Alexandra Caillouet (b) (4) | 10 Mar 2021 17:58:04 |

US3362244

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:14:58

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:32:16 |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| User entered '3 Feb 2021' | Alexandra Caillouet (b) (4) | 10 Mar 2021 17:58:04 |

US3362244

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:14:58

[Collection time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:32:16 |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| User entered '10:54' | Alexandra Caillouet (b) (4) | 10 Mar 2021 17:58:04 |

US3362244

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:32:16 |
| User entered '3 Feb 2021 10:54' | System | 10 Mar 2021 17:58:04 |

US3362244

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:14:58

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:32:16 |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| User entered 'Yes (Y)' | Alexandra Caillouet (b) (4) | 03 Feb 2021 17:39:14 |

US3362244

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:14:58

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:32:16 |
| User entered 'I' | System | 03 Feb 2021 17:39:14 |

US3362244

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:14:58

[Did the participant experience any adverse events?](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 06:00:37 |
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) | 05 Nov 2020 17:53:11 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Crystal Rowell (b) (4) | 02 Oct 2020 19:16:29 |
| User entered 'No (N)' | (b) (4), (b) (6) | 25 Aug 2020 19:12:17 |

US3362244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:14:58

[AEID](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 16:39:44 |
| | | |

US3362244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:14:58

[Adverse event](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 16:39:44 |
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Arthropathies NEC, PT: Arthritis, LLT: Coxarthrosis - version MedDRA\\23.0. | Coder Import (b) (4) | 03 Oct 2020 04:15:50 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) | 03 Oct 2020 04:15:50 |
| Data point term sent to Coder | System | 02 Oct 2020 19:19:01 |
| User entered 'worsening of left hip pain/arthritis' | Crystal Rowell (b) (4) | 02 Oct 2020 19:18:55 |

US3362244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:14:58

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 16:39:44 |
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered 'Yes (Y)' | Crystal Rowell (b) (4) | 02 Oct 2020 19:18:55 |
| | (b) (4) | |

US3362244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:14:58

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 16:39:44 |
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered 'No (N)' | Crystal Rowell (b) (4) | 02 Oct 2020 19:18:55 |

US3362244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:14:58

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 16:39:44 |
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered 'No (N)' | Crystal Rowell (b) (4) | 02 Oct 2020 19:18:55 |

US3362244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 16:39:44 |
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered '08 Sep 2020' | Crystal Rowell (b) (4) | 02 Oct 2020 19:18:55 |

US3362244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:14:58

[Start time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 16:39:44 |
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered empty. | Crystal Rowell (b) (4) | 02 Oct 2020 19:18:55 |

US3362244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:14:58

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 16:39:44 |
| User entered empty. | System | 02 Oct 2020 19:18:55 |

US3362244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:14:58

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 16:39:44 |
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered 'No (N)' reason for change: Data Entry Error | Crystal Rowell (b) (4) | 12 Nov 2020 20:51:25 |
| User entered 'Yes (Y)' | (b) (4) | |
| | Crystal Rowell (b) (4) | 02 Oct 2020 19:18:55 |
| | (b) (4) | |

US3362244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:14:58

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 16:39:44 |
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered '11 Nov 2020' reason for change: Data Entry Error | Crystal Rowell (b) (4) | 12 Nov 2020 20:51:25 |
| User entered empty. | Crystal Rowell (b) (4) | 02 Oct 2020 19:18:55 |

US3362244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:14:58

End time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 16:39:44 |
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered empty. | Crystal Rowell (b) (4) | 02 Oct 2020 19:18:55 |

US3362244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:14:58

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 16:39:44 |
| User entered empty. | System | 02 Oct 2020 19:18:55 |

US3362244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:14:58

[Severity](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 16:39:44 |
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' | Crystal Rowell (b) (4) | 02 Oct 2020 19:18:55 |

US3362244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:14:58

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 16:39:44 |
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered 'No (N)' | Crystal Rowell (b) (4) | 02 Oct 2020 19:18:55 |

US3362244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:14:58

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 16:39:44 |
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered '0' | Crystal Rowell (b) (4) | 02 Oct 2020 19:18:55 |
| | (b) (4) | |

US3362244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:14:58

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 16:39:44 |
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered '0' | Crystal Rowell (b) (4) | 02 Oct 2020 19:18:55 |

US3362244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:14:58

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 16:39:44 |
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered '0' | Crystal Rowell (b) (4) | 02 Oct 2020 19:18:55 |

US3362244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:14:58

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 16:39:44 |
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered empty. | Crystal Rowell (b) (4) | 02 Oct 2020 19:18:55 |

US3362244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:14:58

Hospital Discharge Date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 16:39:44 |
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered empty. | Crystal Rowell (b) (4) | 02 Oct 2020 19:18:55 |

US3362244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:14:58

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 16:39:44 |
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered empty. | Crystal Rowell (b) (4) | 02 Oct 2020 19:18:55 |

US3362244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:14:58

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 16:39:44 |
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered empty. | Crystal Rowell (b) (4) | 02 Oct 2020 19:18:55 |

US3362244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:14:58

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 16:39:44 |
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered '0' | Crystal Rowell (b) (4) | 02 Oct 2020 19:18:55 |

US3362244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:14:58

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 16:39:44 |
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered '0' | Crystal Rowell (b) (4) | 02 Oct 2020 19:18:55 |

US3362244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:14:58

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 16:39:44 |
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered '0' | Crystal Rowell (b) (4) | 02 Oct 2020 19:18:55 |

US3362244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:14:58

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 16:39:44 |
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered 'Not Related (NOT RELATED)' | Crystal Rowell (b) (4) | 02 Oct 2020 19:18:55 |
| | (b) (4) | |

US3362244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:14:58

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 16:39:44 |
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered 'Not Related (NOT RELATED)' | Crystal Rowell (b) (4) | 02 Oct 2020 19:18:55 |

US3362244

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:14:58

Action taken with investigational product

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 16:39:44 |
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System). | System | 25 Jan 2021 23:14:01 |
| Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered by data change (Site from System). | System | 25 Jan 2021 23:14:01 |
| User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System). | System | 25 Jan 2021 23:05:40 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User closed query 'Per CDM: there are more than 1 record with action of IP Withdrawn. Please review and reconcile as the main reason (only 1 record) for IP Withdrawn should be recorded.' (Site from DM). | (b) (4), (b) (6) | 19 Nov 2020 14:47:12 |
| Query 'Per CDM: there are more than 1 record with action of IP Withdrawn. Please review and reconcile as the main reason (only 1 record) for IP Withdrawn should be recorded.' answered with 'updated' (Site from DM). | Crystal Rowell (b) (4) | 19 Nov 2020 13:05:35 |
| User opened query 'Per CDM: there are more than 1 record with action of IP Withdrawn. Please review and reconcile as the main reason (only 1 record) for IP Withdrawn should be recorded.' (Site from DM). | (b) (4), (b) (6) | 18 Nov 2020 22:44:03 |
| User closed query 'Per CDM re-query: Thank you for your answer. Please review and clarify "Dosing discontinuation" start date because AE started on 08Sep2020, Visit 2 was 23Sep2020 and Withdrawn was 15sep2020. Please clarify and review if this date is correct. Thank you!' (Site from DM). | (b) (4), (b) (6) | 15 Oct 2020 11:49:21 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:14:58

Action taken with investigational product

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Query 'Per CDM re-query: Thank you for your answer. Please review and clarify "Dosing discontinuation" start date because AE started on 08Sep2020, Visit 2 was 23Sep2020 and Withdrawn was 15sep2020. Please clarify and review if this date is correct. Thank you!' answered with 'Please clarify where you are seeing 15SEP2020 as discontinuation/withdrawn date. ' (Site from DM). | (b) (4), (b) (6) | 14 Oct 2020 22:11:54 |
| User opened query 'Per CDM re-query: Thank you for your answer. Please review and clarify "Dosing discontinuation" start date because AE started on 08Sep2020, Visit 2 was 23Sep2020 and Withdrawn was 15sep2020. Please clarify and review if this date is correct. Thank you!' (Site from DM). | (b) (4), (b) (6) | 09 Oct 2020 08:26:49 |
| User closed query 'Per CDM: "Action taken with investigational product" is answered as "Investigational product withdrawn", however no "Dosing discontinuation" is entered. Please consider entering proper "End of Study" forms. Thank you!' (Site from DM). | (b) (4), (b) (6) | 09 Oct 2020 08:26:49 |
| Query 'Per CDM: "Action taken with investigational product" is answered as "Investigational product withdrawn", however no "Dosing discontinuation" is entered. Please consider entering proper "End of Study" forms. Thank you!' answered with 'applicable EOS forms have been updated' (Site from DM). | (b) (4), (b) (6) | 08 Oct 2020 16:10:31 |
| User opened query 'Per CDM: "Action taken with investigational product" is answered as "Investigational product withdrawn", however no "Dosing discontinuation" is entered. Please consider entering proper "End of Study" forms. Thank you!' (Site from DM). | (b) (4), (b) (6) | 08 Oct 2020 13:17:32 |
| User entered 'Investigational Product Withdrawn (WITHDRAWN)' | Crystal Rowell (b) (4) (b) (4) | 02 Oct 2020 19:18:55 |

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Folder: Adverse Events

Form: Adverse Events (1)

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[None](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 16:39:44 |
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered '0' | Crystal Rowell (b) (4) | 02 Oct 2020 19:18:55 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:14:58

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 16:39:44 |
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered 'l' | Crystal Rowell (b) (4) | 02 Oct 2020 19:18:55 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:14:58

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 16:39:44 |
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| User closed query 'Per CDM: Response noted, please leave this query open and update when data becomes available or comment accordingly. ' (Site from DM). | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 04:26:38 |
| Query 'Per CDM: Response noted, please leave this query open and update when data becomes available or comment accordingly. ' answered with 'con procedure noted on 29Sep2020' (Site from DM). | Crystal Rowell (b) (4) (b) (4) | 20 Nov 2020 16:43:18 |
| User opened query 'Per CDM: Response noted, please leave this query open and update when data becomes available or comment accordingly. ' (Site from DM). | (b) (4), (b) (6) | 19 Nov 2020 21:03:37 |
| User closed query 'Per DM CLR: Treatment Required = 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 Nov 2020 21:03:37 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| Query 'Per DM CLR: Treatment Required = 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 medical records' (Site from DM). | (b) (4), (b) (6) | 30 Oct 2020 16:37:24 |
| User opened query 'Per DM CLR: Treatment Required = 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) | 30 Oct 2020 03:48:56 |
| User entered 'I' | Crystal Rowell (b) (4) (b) (4) | 02 Oct 2020 19:18:55 |

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Folder: Adverse Events

Form: Adverse Events (1)

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[Outcome](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 16:39:44 |
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error | Crystal Rowell (b) (4) | 12 Nov 2020 20:51:25 |
| User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' | Crystal Rowell (b) (4) | 02 Oct 2020 19:18:55 |

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 16:39:44 |
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered empty. | Crystal Rowell (b) (4) | 02 Oct 2020 19:18:55 |

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 16:39:44 |
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered empty. | Crystal Rowell (b) (4) | 02 Oct 2020 19:18:55 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:14:58

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 16:39:44 |
| User entered '0' | System | 02 Oct 2020 19:18:55 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:14:58

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 16:39:44 |
| User entered 'I' | System | 02 Oct 2020 19:18:55 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:14:58

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 16:39:44 |
| | | |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:14:58

[AEID](#)

| Audit | User | Time (GMT) |
|---------------------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| Reviewed for Safety. | (b) (4), (b) (6) | 29 Oct 2020 18:59:24 |
| User entered | | |
| 'USA-US112-2020-mRNA-1273-P301000006' | System | 29 Oct 2020 18:59:17 |
| User entered 'New' | (b) (4), (b) (6) | 29 Oct 2020 18:59:17 |
| | | |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:14:58

[Adverse event](#)

| Audit | User | Time (GMT) |
|---|-----------------------------------|----------------------|
| User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Infections NEC, PT: Postoperative abscess, LLT: Postoperative abscess - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 13 Mar 2021 22:20:50 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 13 Mar 2021 22:20:50 |
| Data point term sent to Coder | System | 13 Mar 2021 22:19:56 |
| User signature succeeded. | Jordan Whatley (b) (4) (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Infections NEC, PT: Postoperative abscess, LLT: Postoperative abscess - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 11 Nov 2020 00:51:45 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 11 Nov 2020 00:51:45 |
| Data point term sent to Coder | System | 30 Oct 2020 18:58:23 |
| Coding entries removed. | Crystal Rowell (b) (4) (b) (4) | 30 Oct 2020 18:58:03 |
| User entered 'Post operative intra-abdominal aBCESS' reason for change: Data Entry Error | Crystal Rowell (b) (4) (b) (4) | 30 Oct 2020 18:58:03 |
| User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Bone and joint infections, PT: Joint abscess, LLT: Joint abscess - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 17 Oct 2020 09:54:59 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 17 Oct 2020 09:54:59 |
| Data point term sent to Coder | System | 16 Oct 2020 18:42:15 |
| User entered 'LEFT HIP ABSCESS' | (b) (4), (b) (6) | 16 Oct 2020 18:42:13 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:14:58

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 16 Oct 2020 18:42:13 |
| | | |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:14:58

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered 'No (N)' | (b) (4), (b) (6) | 16 Oct 2020 18:42:13 |
| | | |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:14:58

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered 'No (N)' | (b) (4), (b) (6) | 16 Oct 2020 18:42:13 |
| | | |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered '12 Oct 2020' | (b) (4), (b) (6) | 16 Oct 2020 18:42:13 |
| | | |

US3362244

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:14:58

[Start time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered empty. | (b) (4), (b) (6) | 16 Oct 2020 18:42:13 |
| | | |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:14:58

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 16 Oct 2020 18:42:13 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:14:58

[Ongoing?](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| 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. Please leave query open until information is available.' (Site from Safety). | (b) (4) (b) (4), (b) (6) | 15 Dec 2020 15:24:25 |
| 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. Please leave query open until information is available.' answered with 'updated ' (Site from Safety). | Crystal Rowell (b) (4) (b) (4) | 14 Dec 2020 20:38:26 |
| DataPoint Un-verified. | Crystal Rowell (b) (4) (b) (4) | 14 Dec 2020 20:36:33 |
| User entered 'No (N)' reason for change: Data Entry Error | Crystal Rowell (b) (4) (b) (4) | 14 Dec 2020 20:36:33 |
| 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. Please leave query open until information is available.' (Site from Safety). | (b) (4), (b) (6) | 20 Nov 2020 22:14:57 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Crystal Rowell (b) (4) (b) (4) | 28 Oct 2020 21:10:35 |
| User entered 'No (N)' | (b) (4), (b) (6) | 16 Oct 2020 18:42:13 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:14:58

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| User entered '13 Oct 2020' reason for change: Data Entry Error | (b) (4) | 07 Jan 2021 19:29:18 |
| DataPoint Un-verified. | (b) (4), (b) (6) | |
| | Crystal Rowell (b) (4) | 14 Dec 2020 20:36:33 |
| | (b) (4) | |
| User entered '24 Nov 2020' reason for change: Data Entry Error | Crystal Rowell (b) (4) | 14 Dec 2020 20:36:33 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| | (b) (4), (b) (6) | 11 Nov 2020 17:29:45 |
| 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. Please leave query open until information is available.' (Site from Safety). | | |
| 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. Please leave query open until information is available.' answered with 'Patient is receiving outpatient antibiotics ' (Site from Safety). | Crystal Rowell (b) (4) | 10 Nov 2020 21:07:42 |
| | (b) (4) | |
| 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. Please leave query open until information is available.' (Site from Safety). | (b) (4), (b) (6) | 10 Nov 2020 13:57:50 |
| | | |
| 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) | 09 Nov 2020 20:17:57 |
| | | |
| 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 'ok, will update' (Site from Safety). | (b) (4), (b) (6) | 06 Nov 2020 19:57:11 |
| | | |
| 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) | 06 Nov 2020 17:35:12 |
| | | |

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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) |
|---|-----------------------------------|----------------------|
| User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System). | System | 28 Oct 2020 21:10:35 |
| Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System). | System | 28 Oct 2020 21:10:35 |
| User entered empty; reason for change Data Entry Error | Crystal Rowell (b) (4) (b) (4) | 28 Oct 2020 21:10:35 |
| User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System). | System | 28 Oct 2020 21:08:20 |
| User entered '13 Oct 2020' | (b) (4), (b) (6) (b) (4) | 16 Oct 2020 18:42:13 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:14:58

[End time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered empty. | (b) (4), (b) (6) | 16 Oct 2020 18:42:13 |
| | | |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:14:58

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 16 Oct 2020 18:42:13 |

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Folder: Adverse Events

Form: Adverse Events (2)

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[Severity](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered 'Grade 4 (Grade 4)' reason for change: | Crystal Rowell (b) (4) | 28 Oct 2020 21:08:20 |
| Data Entry Error | (b) (4) | |
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' | (b) (4), (b) (6) | 16 Oct 2020 18:42:13 |
| | | |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:14:58

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| 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 | 28 Oct 2020 21:10:13 |
| 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 | 28 Oct 2020 21:08:20 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Crystal Rowell (b) (4) | 28 Oct 2020 21:08:20 |
| User entered 'No (N)' | (b) (4) | |
| | (b) (4), (b) (6) | 16 Oct 2020 18:42:13 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:14:58

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered '0' | (b) (4), (b) (6) | 16 Oct 2020 18:42:13 |
| | | |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:14:58

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered '0' | (b) (4), (b) (6) | 16 Oct 2020 18:42:13 |
| | | |

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Generated On: 09 Jun 2021 17:14:58

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| 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). | | 28 Oct 2020 21:10:13 |
| 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). | | 28 Oct 2020 21:10:13 |
| User entered '1' reason for change: Data Entry Error | Crystal Rowell (b) (4) | 28 Oct 2020 21:10:13 |
| 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) | |
| User entered '0' | System | 28 Oct 2020 21:08:20 |
| | (b) (4), (b) (6) | 16 Oct 2020 18:42:13 |

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Folder: Adverse Events

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Generated On: 09 Jun 2021 17:14:58

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| | | |
| User entered '12 Oct 2020' reason for change: Data Entry Error | Crystal Rowell (b) (4) | 28 Oct 2020 21:08:20 |
| User entered empty. | (b) (4) | |
| | (b) (4), (b) (6) | 16 Oct 2020 18:42:13 |
| | | |

US3362244

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:14:58

Hospital Discharge Date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| | | |
| User entered '20 Oct 2020' reason for change: Data Entry Error | Crystal Rowell (b) (4) | 28 Oct 2020 21:08:20 |
| | (b) (4) | |
| User entered empty. | (b) (4), (b) (6) | 16 Oct 2020 18:42:13 |
| | | |

US3362244

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:14:58

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered 'No (N)' reason for change: Data Entry Error | Crystal Rowell (b) (4) | 28 Oct 2020 21:08:20 |
| User entered empty. | (b) (4) | |
| | (b) (4), (b) (6) | 16 Oct 2020 18:42:13 |
| | | |

US3362244

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:14:58

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered empty. | (b) (4), (b) (6) | 16 Oct 2020 18:42:13 |
| | | |

US3362244

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:14:58

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered '0' | (b) (4), (b) (6) | 16 Oct 2020 18:42:13 |
| | | |

US3362244

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:14:58

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered '0' | (b) (4), (b) (6) | 16 Oct 2020 18:42:13 |
| | | |

US3362244

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:14:58

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered '0' | (b) (4), (b) (6) | 16 Oct 2020 18:42:13 |
| | | |

US3362244

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:14:58

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 16 Oct 2020 18:42:48 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 16 Oct 2020 18:42:48 |
| User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error | (b) (4), (b) (6) | 16 Oct 2020 18:42:48 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 16 Oct 2020 18:42:13 |
| User entered empty. | (b) (4), (b) (6) | 16 Oct 2020 18:42:13 |

US3362244

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:14:58

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 16 Oct 2020 18:42:48 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 16 Oct 2020 18:42:48 |
| User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error | (b) (4), (b) (6) | 16 Oct 2020 18:42:48 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 16 Oct 2020 18:42:13 |
| User entered empty. | (b) (4), (b) (6) | 16 Oct 2020 18:42:13 |

US3362244

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:14:58

Action taken with investigational product

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 16 Oct 2020 18:42:48 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 16 Oct 2020 18:42:48 |
| User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error | (b) (4), (b) (6) | 16 Oct 2020 18:42:48 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 16 Oct 2020 18:42:13 |
| User entered empty. | (b) (4), (b) (6) | 16 Oct 2020 18:42:13 |

US3362244

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:14:58

[None](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered '0' | (b) (4), (b) (6) | 16 Oct 2020 18:42:13 |
| | | |

US3362244

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:14:58

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered 'I' | (b) (4), (b) (6) | 16 Oct 2020 18:42:13 |
| | | |

US3362244

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:14:58

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered 'I' | (b) (4), (b) (6) | 16 Oct 2020 18:42:13 |
| | | |

US3362244

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:14:58

[Outcome](#)

| Audit | User | Time (GMT) |
|---|-----------------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety). | (b) (4) (b) (4), (b) (6) | 15 Dec 2020 15:24:31 |
| Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'updated ' (Site from Safety). | Crystal Rowell (b) (4) (b) (4) | 14 Dec 2020 20:38:32 |
| DataPoint Un-verified. | Crystal Rowell (b) (4) (b) (4) | 14 Dec 2020 20:36:33 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: | Crystal Rowell (b) (4) (b) (4) | 14 Dec 2020 20:36:33 |
| Data Entry Error | | |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety). | (b) (4), (b) (6) | 06 Nov 2020 17:36:30 |
| User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: | Crystal Rowell (b) (4) (b) (4) | 28 Oct 2020 21:08:20 |
| Data Entry Error | | |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | (b) (4), (b) (6) | 16 Oct 2020 18:42:13 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:14:58

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered empty. | (b) (4), (b) (6) | 16 Oct 2020 18:42:13 |
| | | |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:14:58

[Narrative](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| User closed query 'PV Query: Please provide the dates and results for the MRI and fluid cultures mentioned in medical records. If not available, please state so in your response.' (Site from Safety). | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 15:05:50 |
| User closed query 'PV Query: CT abdomen and pelvis revealed new, irregular consolidative changes in the left lower lobe suspicious for pneumonia. Was this considered an additional AE/SAE? Please complete eCRF as appropriate if yes.' (Site from Safety). | (b) (4), (b) (6) | 22 Dec 2020 15:05:44 |
| Query 'PV Query: Please provide the dates and results for the MRI and fluid cultures mentioned in medical records. If not available, please state so in your response.' answered with 'not available ' (Site from Safety). | Crystal Rowell (b) (4) (b) (4) | 21 Dec 2020 17:36:30 |
| Query 'PV Query: CT abdomen and pelvis revealed new, irregular consolidative changes in the left lower lobe suspicious for pneumonia. Was this considered an additional AE/SAE? Please complete eCRF as appropriate if yes.' answered with 'no, cleared for no acute process in the long ' (Site from Safety). | Crystal Rowell (b) (4) (b) (4) | 21 Dec 2020 17:36:22 |
| User opened query 'PV Query: Please provide the dates and results for the MRI and fluid cultures mentioned in medical records. If not available, please state so in your response.' (Site from Safety). | (b) (4), (b) (6) | 20 Nov 2020 22:15:59 |
| User opened query 'PV Query: CT abdomen and pelvis revealed new, irregular consolidative changes in the left lower lobe suspicious for pneumonia. Was this considered an additional AE/SAE? Please complete eCRF as appropriate if yes.' (Site from Safety). | (b) (4), (b) (6) | 20 Nov 2020 22:15:41 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety). | (b) (4), (b) (6) | 11 Nov 2020 17:29:38 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:14:58

[Narrative](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety). | (b) (4), (b) (6) | 11 Nov 2020 17:29:32 |
| Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'records have been emailed, where are we to capture requested units and referecne ranges ?' (Site from Safety). | Crystal Rowell (b) (4) | 10 Nov 2020 23:06:43 |
| Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'medical records emailed' (Site from Safety). | Crystal Rowell (b) (4) | 10 Nov 2020 23:05:47 |
| User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety). | (b) (4), (b) (6) | 06 Nov 2020 17:39:58 |
| User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety). | (b) (4), (b) (6) | 06 Nov 2020 17:37:31 |
| User entered 'subject had a planned procedure for repair of left pubic rami due to chronic/worsening arthritis. Procedure went well initially, however abscess developed and required inpatient hospitalization, subject notified staff on 28Oct2020 regarding inpatient treatment' reason for change: Data Entry Error | Crystal Rowell (b) (4) | 28 Oct 2020 21:08:20 |
| User entered empty. | (b) (4), (b) (6) | 16 Oct 2020 18:42:13 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:14:58

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 28 Oct 2020 21:08:20 |
| User entered '0' | System | 16 Oct 2020 18:42:13 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:14:58

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 16 Oct 2020 18:42:13 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:14:58

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '0' | System | 28 Oct 2020 21:08:20 |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:14:58

[AEID](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) | 19 Nov 2020 20:00:16 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:02:22 |
| User entered 'USA-US112-2020-mRNA-1273-P301000006' | | 02 Nov 2020 15:02:07 |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:14:58

[Adverse event](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| User coded data point as SOC: Vascular disorders, HLGT: Embolism and thrombosis, HLT: Peripheral embolism and thrombosis, PT: Axillary vein thrombosis, LLT: Axillary vein thrombosis - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 13 Mar 2021 22:20:47 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 13 Mar 2021 22:20:47 |
| Data point term sent to Coder | System | 13 Mar 2021 22:19:56 |
| User signature succeeded. | Jordan Whatley (b) (4) (b) (4) | 13 Mar 2021 22:19:50 |
| User closed query 'Per MM, please confirm if the subject received second dose of IP and update "treatment 2 date", days from dose 2 date", and "action taken with IP", as appropriate.' (Site from DM). | (b) (4), (b) (6) | 09 Feb 2021 16:36:22 |
| Query 'Per MM, please confirm if the subject received second dose of IP and update "treatment 2 date", days from dose 2 date", and "action taken with IP", as appropriate.' answered with 'Subject received 2nd dose of IP at OL-D1 on 06 Jan 2021.' (Site from DM). | Alexandra Caillouet (b) (4) | 06 Feb 2021 17:49:40 |
| User opened query 'Per MM, please confirm if the subject received second dose of IP and update "treatment 2 date", days from dose 2 date", and "action taken with IP", as appropriate.' (Site from DM). | (b) (4), (b) (6) | 01 Feb 2021 12:41:38 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User coded data point as SOC: Vascular disorders, HLGT: Embolism and thrombosis, HLT: Peripheral embolism and thrombosis, PT: Axillary vein thrombosis, LLT: Axillary vein thrombosis - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 12 Nov 2020 23:45:45 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 12 Nov 2020 23:45:45 |
| User closed query 'PV Query: The event term 'right axillary and brachial deep vein thrombosis' contains multiple event terms. Please consider separating them into separate events.' (Site from Safety). | (b) (4), (b) (6) | 11 Nov 2020 19:48:26 |
| Data point term sent to Coder | System | 11 Nov 2020 17:43:32 |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:14:58

[Adverse event](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| User closed query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms. ' (Site from System). | System | 11 Nov 2020 17:43:06 |
| Query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms. ' answered with 'updated ' (Site from System). | Crystal Rowell (b) (4) | 11 Nov 2020 17:43:06 |
| Query 'PV Query: The event term 'right axillary and brachial deep vein thrombosis' contains multiple event terms. Please consider separating them into separate events.' answered with 'updated ' (Site from Safety). | Crystal Rowell (b) (4) | 11 Nov 2020 17:42:59 |
| Data point term sent to Coder | System | 11 Nov 2020 17:33:06 |
| User entered 'RIGHT AXILLARY DEEP VEIN THROMBOSIS' reason for change: Data Entry Error | Crystal Rowell (b) (4) | 11 Nov 2020 17:32:16 |
| User opened query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms. ' (Site from System). | Coder Import (b) (4) | 11 Nov 2020 14:43:32 |
| User opened query 'PV Query: The event term 'right axillary and brachial deep vein thrombosis' contains multiple event terms. Please consider separating them into separate events.' (Site from Safety). | (b) (4), (b) (6) | 06 Nov 2020 17:33:55 |
| Data point term sent to Coder | System | 30 Oct 2020 19:04:37 |
| User entered 'Right axillary and brachial deep vein thrombosis' | Crystal Rowell (b) (4) | 30 Oct 2020 19:03:48 |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:14:58

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered 'Yes (Y)' | Crystal Rowell (b) (4) (b) (4) | 30 Oct 2020 19:03:48 |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:14:58

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered 'No (N)' | Crystal Rowell (b) (4) (b) (4) | 30 Oct 2020 19:03:48 |

US3362244

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:14:58

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered 'No (N)' | Crystal Rowell (b) (4) (b) (4) | 30 Oct 2020 19:03:48 |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered '19 Oct 2020' | Crystal Rowell (b) (4) (b) (4) | 30 Oct 2020 19:03:48 |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:14:58

[Start time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered empty. | Crystal Rowell (b) (4) | 30 Oct 2020 19:03:48 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:14:58

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 30 Oct 2020 19:03:48 |

US3362244

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:14:58

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| | (b) (4) | |
| User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System). | System | 14 Dec 2020 20:57:05 |
| DataPoint Un-verified. | Crystal Rowell (b) (4) | 14 Dec 2020 20:57:05 |
| | (b) (4) | |
| User entered 'No (N)' reason for change: Data Entry Error | Crystal Rowell (b) (4) | 14 Dec 2020 20:57:05 |
| | (b) (4) | |
| User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System). | System | 14 Dec 2020 20:56:27 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| | | |
| User entered 'Yes (Y)' | Crystal Rowell (b) (4) | 30 Oct 2020 19:03:48 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:14:58

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| User entered '05 Nov 2020' reason for change: Data Entry Error | (b) (4) | 07 Jan 2021 19:35:02 |
| 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) | 15 Dec 2020 15:23:42 |
| 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 'updated' (Site from Safety). | Crystal Rowell (b) (4) | 14 Dec 2020 20:56:53 |
| User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System). | (b) (4) | |
| Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System). | System | 14 Dec 2020 20:56:42 |
| User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System). | System | 14 Dec 2020 20:56:42 |
| DataPoint Un-verified. | System | 14 Dec 2020 20:56:27 |
| User entered '19 Nov 2020' reason for change: Data Entry Error | Crystal Rowell (b) (4) | 14 Dec 2020 20:56:27 |
| DataPoint Verified. | (b) (4) | |
| 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) | 19 Nov 2020 20:00:16 |
| User entered empty. | (b) (4), (b) (6) | 06 Nov 2020 17:34:30 |
| | Crystal Rowell (b) (4) | 30 Oct 2020 19:03:48 |
| | (b) (4) | |

US3362244

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:14:58

[End time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered empty. | Crystal Rowell (b) (4) | 30 Oct 2020 19:03:48 |
| | (b) (4) | |

US3362244

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:14:58

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 30 Oct 2020 19:03:48 |

US3362244

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:14:58

[Severity](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered 'Grade 4 (Grade 4)' | Crystal Rowell (b) (4) (b) (4) | 30 Oct 2020 19:03:48 |

US3362244

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:14:58

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered 'Yes (Y)' | Crystal Rowell (b) (4) (b) (4) | 30 Oct 2020 19:03:48 |

US3362244

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:14:58

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered '0' | Crystal Rowell (b) (4) | 30 Oct 2020 19:03:48 |
| | (b) (4) | |

US3362244

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:14:58

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered 'I' | Crystal Rowell (b) (4) | 30 Oct 2020 19:03:48 |
| | (b) (4) | |

US3362244

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:14:58

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| | | |
| User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System). | System | 30 Oct 2020 19:04:05 |
| Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System). | | 30 Oct 2020 19:04:05 |
| User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System). | System | 30 Oct 2020 19:03:48 |
| User entered '0' | Crystal Rowell (b) (4) | 30 Oct 2020 19:03:48 |
| | (b) (4) | |

US3362244

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:14:58

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered empty. | Crystal Rowell (b) (4) | 30 Oct 2020 19:03:48 |
| | (b) (4) | |

US3362244

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:14:58

Hospital Discharge Date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered empty. | Crystal Rowell (b) (4) (b) (4) | 30 Oct 2020 19:03:48 |

US3362244

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:14:58

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered empty; reason for change Data Entry Error | Crystal Rowell (b) (4) | 30 Oct 2020 19:04:05 |
| User entered 'No (N)' | (b) (4) | |
| | Crystal Rowell (b) (4) | 30 Oct 2020 19:03:48 |
| | (b) (4) | |

US3362244

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:14:58

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered empty. | Crystal Rowell (b) (4) (b) (4) | 30 Oct 2020 19:03:48 |

US3362244

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:14:58

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered '0' | Crystal Rowell (b) (4) | 30 Oct 2020 19:03:48 |
| | (b) (4) | |

US3362244

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:14:58

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered '0' | Crystal Rowell (b) (4) | 30 Oct 2020 19:03:48 |
| | (b) (4) | |

US3362244

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:14:58

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered '0' | Crystal Rowell (b) (4) | 30 Oct 2020 19:03:48 |
| | (b) (4) | |

US3362244

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:14:58

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered 'Not Related (NOT RELATED)' | Crystal Rowell (b) (4) (b) (4) | 30 Oct 2020 19:03:48 |

US3362244

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:14:58

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered 'Not Related (NOT RELATED)' | Crystal Rowell (b) (4) (b) (4) | 30 Oct 2020 19:03:48 |

US3362244

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:14:58

Action taken with investigational product

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User closed query 'PV Query: Please confirm action taken. Reported as not applicable for event "post operative intra-abdominal abscess" with onset of 12 Oct 2020, but reported as withdrawn for event "right axillary and brachial deep vein thrombosis" with onset of 19 Oct 2020. Additionally, per day 29 exposure, the subject withdrew consent due to orthopedic surgery needed.' (Site from Safety). | (b) (4), (b) (6) | 11 Nov 2020 19:48:32 |
| Query 'PV Query: Please confirm action taken. Reported as not applicable for event "post operative intra-abdominal abscess" with onset of 12 Oct 2020, but reported as withdrawn for event "right axillary and brachial deep vein thrombosis" with onset of 19 Oct 2020. Additionally, per day 29 exposure, the subject withdrew consent due to orthopedic surgery needed.' answered with 'updated to not applicable as patient withdrew consent for IP prior to AE' (Site from Safety). | Crystal Rowell (b) (4) | 11 Nov 2020 17:42:43 |
| | (b) (4) | |
| User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error | Crystal Rowell (b) (4) | 11 Nov 2020 17:42:10 |
| | (b) (4) | |
| User opened query 'PV Query: Please confirm action taken. Reported as not applicable for event "post operative intra-abdominal abscess" with onset of 12 Oct 2020, but reported as withdrawn for event "right axillary and brachial deep vein thrombosis" with onset of 19 Oct 2020. Additionally, per day 29 exposure, the subject withdrew consent due to orthopedic surgery needed.' (Site from Safety). | (b) (4), (b) (6) | 06 Nov 2020 17:39:20 |
| | | |
| User entered 'Investigational Product Withdrawn (WITHDRAWN)' | Crystal Rowell (b) (4) | 30 Oct 2020 19:03:48 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:14:58

[None](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered '0' | Crystal Rowell (b) (4) | 30 Oct 2020 19:03:48 |
| | (b) (4) | |

US3362244

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:14:58

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered 'I' | Crystal Rowell (b) (4) | 30 Oct 2020 19:03:48 |
| | (b) (4) | |

US3362244

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:14:58

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered '0' | Crystal Rowell (b) (4) | 30 Oct 2020 19:03:48 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:14:58

[Outcome](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety). | (b) (4) (b) (4), (b) (6) | 15 Dec 2020 15:23:48 |
| Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'updated' (Site from Safety). | Crystal Rowell (b) (4) (b) (4) | 14 Dec 2020 20:57:14 |
| DataPoint Un-verified. | Crystal Rowell (b) (4) (b) (4) | 14 Dec 2020 20:56:42 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: | Crystal Rowell (b) (4) (b) (4) | 14 Dec 2020 20:56:42 |
| Data Entry Error | | |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error | Crystal Rowell (b) (4) (b) (4) | 11 Nov 2020 17:47:03 |
| User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety). | (b) (4), (b) (6) | 06 Nov 2020 17:41:44 |
| User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' | Crystal Rowell (b) (4) (b) (4) | 30 Oct 2020 19:03:48 |

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Folder: Adverse Events

Form: Adverse Events (3)

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered empty. | Crystal Rowell (b) (4) (b) (4) | 30 Oct 2020 19:03:48 |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:14:58

[Narrative](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| User closed query 'Per CDM CLR re-query: Thank you for your answer. However, there are still no updates made on Concomitant Procedure form. Please consider adding this under Concomitant Procedure form. Thank you!' (Site from DM). | (b) (4) | |
| Query 'Per CDM CLR re-query: Thank you for your answer. However, there are still no updates made on Concomitant Procedure form. Please consider adding this under Concomitant Procedure form. Thank you!' answered with 'concomitant procedure #3 and #4 added' (Site from DM). | (b) (4), (b) (6) | 25 Jan 2021 14:54:48 |
| User opened query 'Per CDM CLR re-query: Thank you for your answer. However, there are still no updates made on Concomitant Procedure form. Please consider adding this under Concomitant Procedure form. Thank you!' (Site from DM). | Amy Thomassie (b) (4) | 23 Jan 2021 20:08:28 |
| User closed query 'Per DM CLR: SAE Narrative = SUBJECT HAD PICC LINE PLACED POST SURGERY. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF.' | (b) (4) | |
| ' (Site from DM). | | |
| Query 'Per DM CLR: SAE Narrative = SUBJECT HAD PICC LINE PLACED POST SURGERY. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF.' | (b) (4), (b) (6) | 22 Jan 2021 08:49:51 |
| ' answered with 'will update' (Site from DM). | | |
| User opened query 'Per DM CLR: SAE Narrative = SUBJECT HAD PICC LINE PLACED POST SURGERY. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF.' | (b) (4), (b) (6) | 22 Jan 2021 08:49:51 |
| ' (Site from DM). | | |
| User closed query 'PV Query: CT abdomen and pelvis revealed new, irregular consolidative changes in the left lower lobe suspicious for pneumonia. Was this considered an additional AE/SAE? Please complete eCRF as appropriate if yes.' (Site from Safety). | (b) (4), (b) (6) | 12 Jan 2021 21:09:56 |
| | (b) (4) | |
| | | |
| | (b) (4), (b) (6) | 11 Jan 2021 05:56:14 |
| | | |
| | | |
| | (b) (4), (b) (6) | 22 Dec 2020 15:06:25 |

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:14:58

[Narrative](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Query 'PV Query: CT abdomen and pelvis revealed new, irregular consolidative changes in the left lower lobe suspicious for pneumonia. Was this considered an additional AE/SAE? Please complete eCRF as appropriate if yes.' answered with 'no, cleared of acute chest process' (Site from Safety). | Crystal Rowell (b) (4) | 21 Dec 2020 17:38:11 |
| User closed query 'PV Query: Please provide the dates and results for the MRI and fluid cultures mentioned in medical records. If not available, please state so in your response.' (Site from Safety). | (b) (4), (b) (6) | 21 Dec 2020 16:15:57 |
| Query 'PV Query: Please provide the dates and results for the MRI and fluid cultures mentioned in medical records. If not available, please state so in your response.' answered with 'results not available' (Site from Safety). | Crystal Rowell (b) (4) | 18 Dec 2020 22:39:20 |
| User opened query 'PV Query: Please provide the dates and results for the MRI and fluid cultures mentioned in medical records. If not available, please state so in your response.' (Site from Safety). | (b) (4), (b) (6) | 18 Dec 2020 17:58:40 |
| User opened query 'PV Query: CT abdomen and pelvis revealed new, irregular consolidative changes in the left lower lobe suspicious for pneumonia. Was this considered an additional AE/SAE? Please complete eCRF as appropriate if yes.' (Site from Safety). | (b) (4), (b) (6) | 18 Dec 2020 17:58:27 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety). | (b) (4), (b) (6) | 11 Nov 2020 19:48:42 |
| Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'medical records have been emailed, where do we put lab and diagnostic test results?' (Site from Safety). | Crystal Rowell (b) (4) | 11 Nov 2020 17:36:32 |
| User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety). | (b) (4), (b) (6) | 06 Nov 2020 17:38:17 |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:14:58

[Narrative](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| User entered 'Subject had PICC line placed post surgery, note to have pain on 10/19/2020 diagnosed with DVT and PICC line removed, on anti-coagulants' | Crystal Rowell (b) (4) (b) (4) | 30 Oct 2020 19:03:48 |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:14:58

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 30 Oct 2020 19:03:48 |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:14:58

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 30 Oct 2020 19:03:48 |

US3362244

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:14:58

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '0' | System | 30 Oct 2020 19:03:48 |

US3362244

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:14:58

[AEID](#)

| Audit | User | Time (GMT) |
|---------------------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:04 |
| | | |
| User entered | System | 02 Nov 2020 15:03:44 |
| 'USA-US112-2020-mRNA-1273-P301000007' | | |
| User entered 'New' | (b) (4), (b) (6) | 02 Nov 2020 15:03:44 |
| | | |
| | | |

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:14:58

[Adverse event](#)

| Audit | User | Time (GMT) |
|---|-----------------------------------|----------------------|
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Fractures, HLT: Fracture complications, PT: Fracture nonunion, LLT: Fracture nonunion - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 13 Mar 2021 22:20:46 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 13 Mar 2021 22:20:46 |
| Data point term sent to Coder | System | 13 Mar 2021 22:19:51 |
| User signature succeeded. | Jordan Whatley (b) (4) (b) (4) | 13 Mar 2021 22:19:50 |
| User closed query 'Per CDM CLR re-query: Thank you for your answer. However, MH and AE does not match with dates. Please review every single MH and AE related with that issue and update dates correctly. Thank you!' (Site from DM). | (b) (4), (b) (6) | 25 Jan 2021 15:08:08 |
| Query 'Per CDM CLR re-query: Thank you for your answer. However, MH and AE does not match with dates. Please review every single MH and AE related with that issue and update dates correctly. Thank you!' answered with 'The medical condition began unFEB 2020 and worsened 09SEP2020. Therefore, the dates will not match. ' (Site from DM). | Amy Thomassie (b) (4) (b) (4) | 23 Jan 2021 20:04:21 |
| User opened query 'Per CDM CLR re-query: Thank you for your answer. However, MH and AE does not match with dates. Please review every single MH and AE related with that issue and update dates correctly. Thank you!' (Site from DM). | (b) (4), (b) (6) | 22 Jan 2021 12:34:48 |
| User closed query 'Per DM CLR - RQ: Site's response noted. However, the baseline condition is already resolved on APR2020. Please review and reconcile eCRFs as appropriate.' (Site from DM). | (b) (4), (b) (6) | 22 Jan 2021 12:34:48 |
| Query 'Per DM CLR - RQ: Site's response noted. However, the baseline condition is already resolved on APR2020. Please review and reconcile eCRFs as appropriate.' answered with 'stop date of medical history removed. ' (Site from DM). | Amy Thomassie (b) (4) (b) (4) | 12 Jan 2021 21:47:21 |
| User opened query 'Per DM CLR - RQ: Site's response noted. However, the baseline condition is already resolved on APR2020. Please review and reconcile eCRFs as appropriate.' (Site from DM). | (b) (4), (b) (6) | 11 Jan 2021 05:57:15 |

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:14:58

[Adverse event](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| User closed query 'Per DM CLR: Worsening AE is noted, but no baseline medical history or adverse event condition is found. Please confirm if this is a worsening; if yes, please add baseline Medical history or prior AE to the appropriate page as applicable. ' (Site from DM). | (b) (4), (b) (6) | 17 Dec 2020 19:26:14 |
| Query 'Per DM CLR: Worsening AE is noted, but no baseline medical history or adverse event condition is found. Please confirm if this is a worsening; if yes, please add baseline Medical history or prior AE to the appropriate page as applicable. | Crystal Rowell (b) (4) | 16 Dec 2020 17:06:56 |
| ' answered with 'updated, was listed as fractured pelvis under medical history' (Site from DM). | (b) (4) | |
| User opened query 'Per DM CLR: Worsening AE is noted, but no baseline medical history or adverse event condition is found. Please confirm if this is a worsening; if yes, please add baseline Medical history or prior AE to the appropriate page as applicable. | (b) (4), (b) (6) | 24 Nov 2020 10:58:40 |
| ' (Site from DM). | | |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Fractures, HLT: Fracture complications, PT: Fracture nonunion, LLT: Fracture nonunion - version MedDRA\23.0. | Coder Import (b) (4) | 10 Nov 2020 22:55:47 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0. | (b) (4) | |
| User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Pelvic fractures and dislocations, PT: Pelvic fracture, LLT: Pubic rami fracture - version MedDRA\23.0. | Coder Import (b) (4) | 10 Nov 2020 22:55:47 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0. | (b) (4) | |
| Data point term sent to Coder | System | 30 Oct 2020 19:16:56 |
| User entered 'Worsening of anterior left pelvic ring non-union' | Crystal Rowell (b) (4) | 30 Oct 2020 19:16:53 |
| | (b) (4) | |

US3362244

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:14:58

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered 'Yes (Y)' | Crystal Rowell (b) (4) (b) (4) | 30 Oct 2020 19:16:53 |

US3362244

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:14:58

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered 'No (N)' | Crystal Rowell (b) (4) | 30 Oct 2020 19:16:53 |
| | (b) (4) | |

US3362244

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:14:58

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered 'No (N)' | Crystal Rowell (b) (4) | 30 Oct 2020 19:16:53 |
| | (b) (4) | |

US3362244

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| | | |
| User entered '09 Sep 2020' reason for change: Data Entry Error | Crystal Rowell (b) (4) | 12 Nov 2020 19:56:50 |
| | (b) (4) | |
| User entered '29 Sep 2020' | Crystal Rowell (b) (4) | 30 Oct 2020 19:16:53 |
| | (b) (4) | |

US3362244

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:14:58

[Start time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered empty. | Crystal Rowell (b) (4) | 30 Oct 2020 19:16:53 |
| | (b) (4) | |

US3362244

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:14:58

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 30 Oct 2020 19:16:53 |

US3362244

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:14:58

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered 'No (N)' | Crystal Rowell (b) (4) (b) (4) | 30 Oct 2020 19:16:53 |

US3362244

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:14:58

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| | | |
| User entered '05 Oct 2020' reason for change: Data Entry Error | Crystal Rowell (b) (4) | 09 Nov 2020 22:02:20 |
| | (b) (4) | |
| User entered '5 Oct 2020' | Crystal Rowell (b) (4) | 30 Oct 2020 19:16:53 |
| | (b) (4) | |

US3362244

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:14:58

[End time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered empty. | Crystal Rowell (b) (4) | 30 Oct 2020 19:16:53 |
| | (b) (4) | |

US3362244

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:14:58

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 30 Oct 2020 19:16:53 |

US3362244

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:14:58

[Severity](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered 'Grade 4 (Grade 4)' | Crystal Rowell (b) (4) | 30 Oct 2020 19:16:53 |
| | (b) (4) | |

US3362244

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:14:58

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 30 Oct 2020 19:17:06 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 30 Oct 2020 19:17:06 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Crystal Rowell (b) (4) | 30 Oct 2020 19:17:06 |
| | (b) (4) | |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 30 Oct 2020 19:16:53 |
| User entered empty. | Crystal Rowell (b) (4) | 30 Oct 2020 19:16:53 |
| | (b) (4) | |

US3362244

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:14:58

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered '0' | Crystal Rowell (b) (4) | 30 Oct 2020 19:16:53 |
| | (b) (4) | |

US3362244

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:14:58

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered '0' | Crystal Rowell (b) (4) | 30 Oct 2020 19:16:53 |
| | (b) (4) | |

US3362244

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:14:58

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered 'I' | Crystal Rowell (b) (4) | 30 Oct 2020 19:16:53 |
| | (b) (4) | |

US3362244

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:14:58

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| | | |
| User entered '29 Sep 2020' reason for change: Data Entry Error | Crystal Rowell (b) (4) | 30 Oct 2020 19:17:25 |
| | (b) (4) | |
| User entered '29 Oct 2020' | Crystal Rowell (b) (4) | 30 Oct 2020 19:16:53 |
| | (b) (4) | |

US3362244

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:14:58

Hospital Discharge Date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User closed query 'Hospital discharge date is prior to Hospital admission date. Please correct. ' (Site from System). | System | 30 Oct 2020 19:17:25 |
| Query 'Hospital discharge date is prior to Hospital admission date. Please correct. ' answered by data change (Site from System). | System | 30 Oct 2020 19:17:25 |
| User opened query 'Hospital discharge date is prior to Hospital admission date. Please correct. ' (Site from System). | System | 30 Oct 2020 19:16:53 |
| User entered '5 Oct 2020' | Crystal Rowell (b) (4) | 30 Oct 2020 19:16:53 |
| | (b) (4) | |

US3362244

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:14:58

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered 'No (N)' | Crystal Rowell (b) (4) (b) (4) | 30 Oct 2020 19:16:53 |

US3362244

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:14:58

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered empty. | Crystal Rowell (b) (4) (b) (4) | 30 Oct 2020 19:16:53 |

US3362244

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:14:58

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered '0' | Crystal Rowell (b) (4) | 30 Oct 2020 19:16:53 |
| | (b) (4) | |

US3362244

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:14:58

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered '0' | Crystal Rowell (b) (4) | 30 Oct 2020 19:16:53 |
| | (b) (4) | |

US3362244

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:14:58

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered '0' | Crystal Rowell (b) (4) | 30 Oct 2020 19:16:53 |
| | (b) (4) | |

US3362244

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:14:58

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered 'Not Related (NOT RELATED)' | Crystal Rowell (b) (4) (b) (4) | 30 Oct 2020 19:16:53 |

US3362244

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:14:58

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered 'Not Related (NOT RELATED)' | Crystal Rowell (b) (4) (b) (4) | 30 Oct 2020 19:16:53 |

US3362244

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:14:58

Action taken with investigational product

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System). | (b) (4) | 25 Jan 2021 23:14:01 |
| Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered by data change (Site from System). | System | 25 Jan 2021 23:14:01 |
| User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System). | System | 25 Jan 2021 23:05:40 |
| User closed query 'PV Query: Action taken with study drug was reported/updated to not applicable. Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn.' (Site from Safety). | (b) (4), (b) (6) | 16 Dec 2020 19:54:49 |
| Query 'PV Query: Action taken with study drug was reported/updated to not applicable. Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn.' answered with 'updated ' (Site from Safety). | Crystal Rowell (b) (4) | 16 Dec 2020 17:07:27 |
| DataPoint Un-verified. | Crystal Rowell (b) (4) | 16 Dec 2020 17:07:18 |
| User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error | Crystal Rowell (b) (4) | 16 Dec 2020 17:07:18 |
| User opened query 'PV Query: Action taken with study drug was reported/updated to not applicable. Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn.' (Site from Safety). | (b) (4), (b) (6) | 25 Nov 2020 22:44:04 |

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:14:58

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error | Crystal Rowell (b) (4) | 19 Nov 2020 13:05:05 |
| User entered 'Investigational Product Withdrawn (WITHDRAWN)' | Crystal Rowell (b) (4) | 30 Oct 2020 19:16:53 |

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:14:58

[None](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered '0' | Crystal Rowell (b) (4) | 30 Oct 2020 19:16:53 |
| | (b) (4) | |

US3362244

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:14:58

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered 'I' | Crystal Rowell (b) (4) | 30 Oct 2020 19:16:53 |
| | (b) (4) | |

US3362244

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:14:58

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered 'I' | Crystal Rowell (b) (4) | 30 Oct 2020 19:16:53 |
| | (b) (4) | |

US3362244

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:14:58

[Outcome](#)

| Audit | User | Time (GMT) |
|---|-----------------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | Crystal Rowell (b) (4) (b) (4) | 30 Oct 2020 19:16:53 |

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:14:58

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered empty. | Crystal Rowell (b) (4) | 30 Oct 2020 19:16:53 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:14:58

[Narrative](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User closed query 'PV Query: Please confirm the event of "worsening of anterior left pelvic ring non-union", occurred after the start of the study.' (Site from Safety). | (b) (4), (b) (6) | 11 Nov 2020 20:28:22 |
| User closed query 'PV Query: Was the procedure for the repair of anterior left pelvic ring a planned procedure (prior to starting the study)?' (Site from Safety). | (b) (4), (b) (6) | 11 Nov 2020 20:28:19 |
| User closed query 'PV Query: If the worsening of anterior left pelvic ring non-union occurred prior to the start of the study, and the repair of anterior left pelvic was a planned hospitalization, please consider deleting the event. If to remain as a SAE, please explain.' (Site from Safety). | (b) (4), (b) (6) | 11 Nov 2020 20:28:15 |
| User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety). | (b) (4), (b) (6) | 11 Nov 2020 20:27:55 |
| User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety). | (b) (4), (b) (6) | 11 Nov 2020 20:27:51 |
| 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) | 11 Nov 2020 20:27:47 |

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:14:58

[Narrative](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Query 'PV Query: If the worsening of anterior left pelvic ring non-union occurred prior to the start of the study, and the repair of anterior left pelvic was a planned hospitalization, please consider deleting the event. If to remain as a SAE, please explain.' answered with 'the patient reported worsening hip pain initially and withdrew IP consent, went to ortho for evaluation of worsening hip pain and it was noted that there was worsening of non-union, no complete healing from original injury' (Site from Safety). | Crystal Rowell (b) (4) | 11 Nov 2020 17:57:05 |
| Query 'PV Query: Please confirm the event of "worsening of anterior left pelvic ring non-union", occurred after the start of the study.' answered with 'yes, confirmed started after study start' (Site from Safety). | Crystal Rowell (b) (4) | 11 Nov 2020 17:53:03 |
| Query 'PV Query: Was the procedure for the repair of anterior left pelvic ring a planned procedure (prior to starting the study)?' answered with 'no, patient reported previous fracture and chronic arthritic pain at study onset' (Site from Safety). | Crystal Rowell (b) (4) | 11 Nov 2020 17:52:41 |
| Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'updated' (Site from Safety). | Crystal Rowell (b) (4) | 11 Nov 2020 17:50:43 |
| Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'medical records have been sent to safety, where do we record this information?' (Site from Safety). | Crystal Rowell (b) (4) | 11 Nov 2020 17:50:00 |
| 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 'per review of medical records and per patient, not done' (Site from Safety). | Crystal Rowell (b) (4) | 11 Nov 2020 17:49:27 |

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:14:58

[Narrative](#)

| Audit | User | Time (GMT) |
|---|-----------------------------------|----------------------|
| User opened query 'PV Query: If the worsening of anterior left pelvic ring non-union occurred prior to the start of the study, and the repair of anterior left pelvic was a planned hospitalization, please consider deleting the event. If to remain as a SAE, please explain.' (Site from Safety). | (b) (4), (b) (6) | 09 Nov 2020 22:15:57 |
| User opened query 'PV Query: Please confirm the event of "worsening of anterior left pelvic ring non-union", occurred after the start of the study.' (Site from Safety). | (b) (4), (b) (6) | 09 Nov 2020 22:15:43 |
| User opened query 'PV Query: Was the procedure for the repair of anterior left pelvic ring a planned procedure (prior to starting the study)?' (Site from Safety). | (b) (4), (b) (6) | 09 Nov 2020 22:15:36 |
| User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety). | (b) (4), (b) (6) | 09 Nov 2020 22:15:27 |
| User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety). | (b) (4), (b) (6) | 09 Nov 2020 22:15:21 |
| 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) | 09 Nov 2020 22:15:16 |
| User entered 'patient had planned procedure for repair of anterior left pelvic ring, did not disclose hospitalization.' | Crystal Rowell (b) (4) (b) (4) | 30 Oct 2020 19:16:53 |

US3362244

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:14:58

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 30 Oct 2020 19:17:06 |

US3362244

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:14:58

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 30 Oct 2020 19:16:53 |

US3362244

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:14:58

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '0' | System | 30 Oct 2020 19:16:53 |

US3362244

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:14:58

[AEID](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) | 19 Nov 2020 20:00:16 |
| Reviewed for Safety. | (b) (4), (b) (6) | 11 Nov 2020 19:07:42 |
| User entered 'USA-US112-2020-mRNA-1273-P301000006' | | 11 Nov 2020 19:07:38 |

US3362244

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:14:58

[Adverse event](#)

| Audit | User | Time (GMT) |
|---|-----------------------------------|----------------------|
| User coded data point as SOC: Vascular disorders, HLGT: Embolism and thrombosis, HLT: Peripheral embolism and thrombosis, PT: Deep vein thrombosis, LLT: Deep venous thrombosis arm - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 13 Mar 2021 22:20:48 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 13 Mar 2021 22:20:48 |
| Data point term sent to Coder | System | 13 Mar 2021 22:19:51 |
| User signature succeeded. | Jordan Whatley (b) (4) (b) (4) | 13 Mar 2021 22:19:50 |
| User closed query 'Per MM, please confirm if the subject received second dose of IP and update "treatment 2 date", days from dose 2 date", and "action taken with IP", as appropriate.' (Site from DM). | (b) (4), (b) (6) | 09 Feb 2021 16:36:50 |
| Query 'Per MM, please confirm if the subject received second dose of IP and update "treatment 2 date", days from dose 2 date", and "action taken with IP", as appropriate.' answered with 'Second dose of IP given at OL-D1 visit on 06 Jan 2021. ' (Site from DM). | Alexandra Caillouet (b) (4) | 06 Feb 2021 17:51:15 |
| User opened query 'Per MM, please confirm if the subject received second dose of IP and update "treatment 2 date", days from dose 2 date", and "action taken with IP", as appropriate.' (Site from DM). | (b) (4), (b) (6) | 01 Feb 2021 12:41:52 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User coded data point as SOC: Vascular disorders, HLGT: Embolism and thrombosis, HLT: Peripheral embolism and thrombosis, PT: Deep vein thrombosis, LLT: Deep venous thrombosis arm - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 11 Nov 2020 18:11:37 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 11 Nov 2020 18:11:37 |
| Data point term sent to Coder | System | 11 Nov 2020 17:45:34 |
| User entered 'right brachial deep vein thrombosis' | Crystal Rowell (b) (4) (b) (4) | 11 Nov 2020 17:44:43 |

US3362244

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:14:58

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered 'Yes (Y)' | Crystal Rowell (b) (4) (b) (4) | 11 Nov 2020 17:44:43 |

US3362244

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:14:58

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered 'No (N)' | Crystal Rowell (b) (4) (b) (4) | 11 Nov 2020 17:44:43 |

US3362244

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:14:58

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 11 Nov 2020 17:45:00 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 11 Nov 2020 17:45:00 |
| User entered 'No (N)' reason for change: Data Entry Error | Crystal Rowell (b) (4) | 11 Nov 2020 17:45:00 |
| | (b) (4) | |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 11 Nov 2020 17:44:43 |
| User entered empty. | Crystal Rowell (b) (4) | 11 Nov 2020 17:44:43 |
| | (b) (4) | |

US3362244

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered '19 Oct 2020' | Crystal Rowell (b) (4) | 11 Nov 2020 17:44:43 |
| | (b) (4) | |

US3362244

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:14:58

[Start time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered empty. | Crystal Rowell (b) (4) | 11 Nov 2020 17:44:43 |
| | (b) (4) | |

US3362244

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:14:58

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 11 Nov 2020 17:44:43 |

US3362244

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:14:58

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---|-----------------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| User closed query 'PV Query: SAE # 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) (4), (b) (6) | 15 Dec 2020 15:22:38 |
| Query 'PV Query: SAE # 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 'updated' (Site from Safety). | Crystal Rowell (b) (4) (b) (4) | 14 Dec 2020 20:52:35 |
| DataPoint Un-verified. | Crystal Rowell (b) (4) (b) (4) | 14 Dec 2020 20:52:00 |
| User entered 'No (N)' reason for change: Data Entry Error | Crystal Rowell (b) (4) (b) (4) | 14 Dec 2020 20:52:00 |
| User opened query 'PV Query: SAE # 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) | 20 Nov 2020 22:17:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered 'Yes (Y)' | Crystal Rowell (b) (4) (b) (4) | 11 Nov 2020 17:44:43 |

US3362244

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:14:58

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System). | (b) (4) | 07 Jan 2021 19:41:45 |
| Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System). | System | 07 Jan 2021 19:41:45 |
| User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System). | System | 07 Jan 2021 19:41:23 |
| User entered '05 Nov 2020' reason for change: Data Entry Error | (b) (4), (b) (6) | 07 Jan 2021 19:41:23 |
| DataPoint Un-verified. | Crystal Rowell (b) (4) | 14 Dec 2020 20:52:00 |
| User entered '19 Nov 2020' reason for change: Data Entry Error | (b) (4) | 14 Dec 2020 20:52:00 |
| DataPoint Verified. | Crystal Rowell (b) (4) | 14 Dec 2020 20:52:00 |
| | (b) (4) | |
| | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| | (b) (4) | |
| User entered empty. | Crystal Rowell (b) (4) | 11 Nov 2020 17:44:43 |
| | (b) (4) | |

US3362244

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:14:58

[End time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered empty. | Crystal Rowell (b) (4) | 11 Nov 2020 17:44:43 |
| | (b) (4) | |

US3362244

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:14:58

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 11 Nov 2020 17:44:43 |

US3362244

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:14:58

[Severity](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered 'Grade 4 (Grade 4)' | Crystal Rowell (b) (4) | 11 Nov 2020 17:44:43 |
| | (b) (4) | |

US3362244

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:14:58

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| 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 | 11 Nov 2020 17:45:33 |
| 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 | 11 Nov 2020 17:44:43 |
| User entered 'Yes (Y)' | Crystal Rowell (b) (4) | 11 Nov 2020 17:44:43 |
| | (b) (4) | |

US3362244

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:14:58

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered '0' | Crystal Rowell (b) (4) | 11 Nov 2020 17:44:43 |
| | (b) (4) | |

US3362244

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:14:58

[Life threatening](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered '1' reason for change: Data Entry Error | Crystal Rowell (b) (4) | 11 Nov 2020 17:45:33 |
| | (b) (4) | |
| User entered '0' | Crystal Rowell (b) (4) | 11 Nov 2020 17:44:43 |
| | (b) (4) | |

US3362244

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:14:58

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered '0' | Crystal Rowell (b) (4) | 11 Nov 2020 17:44:43 |
| | (b) (4) | |

US3362244

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:14:58

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered empty. | Crystal Rowell (b) (4) | 11 Nov 2020 17:44:43 |
| | (b) (4) | |

US3362244

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:14:58

Hospital Discharge Date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered empty. | Crystal Rowell (b) (4) | 11 Nov 2020 17:44:43 |
| | (b) (4) | |

US3362244

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:14:58

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered empty. | Crystal Rowell (b) (4) | 11 Nov 2020 17:44:43 |
| | (b) (4) | |

US3362244

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:14:58

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered empty. | Crystal Rowell (b) (4) (b) (4) | 11 Nov 2020 17:44:43 |

US3362244

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:14:58

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered '0' | Crystal Rowell (b) (4) | 11 Nov 2020 17:44:43 |
| | (b) (4) | |

US3362244

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:14:58

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered '0' | Crystal Rowell (b) (4) | 11 Nov 2020 17:44:43 |
| | (b) (4) | |

US3362244

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:14:58

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered '0' | Crystal Rowell (b) (4) | 11 Nov 2020 17:44:43 |
| | (b) (4) | |

US3362244

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:14:58

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered 'Not Related (NOT RELATED)' | Crystal Rowell (b) (4) (b) (4) | 11 Nov 2020 17:44:43 |

US3362244

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:14:58

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered 'Not Related (NOT RELATED)' | Crystal Rowell (b) (4) | 11 Nov 2020 17:44:43 |
| | (b) (4) | |

US3362244

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:14:58

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered 'Not Applicable (NOT APPLICABLE)' | Crystal Rowell (b) (4) (b) (4) | 11 Nov 2020 17:44:43 |

US3362244

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:14:58

[None](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered '0' | Crystal Rowell (b) (4) | 11 Nov 2020 17:44:43 |
| | (b) (4) | |

US3362244

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:14:58

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered 'I' | Crystal Rowell (b) (4) | 11 Nov 2020 17:44:43 |
| | (b) (4) | |

US3362244

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:14:58

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered '0' | Crystal Rowell (b) (4) | 11 Nov 2020 17:44:43 |
| | (b) (4) | |

US3362244

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:14:58

[Outcome](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error | (b) (4) | |
| | (b) (4), (b) (6) | 07 Jan 2021 19:41:45 |
| User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error | (b) (4), (b) (6) | 07 Jan 2021 19:41:23 |
| User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety). | (b) (4), (b) (6) | 15 Dec 2020 15:22:43 |
| Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'updated' (Site from Safety). | Crystal Rowell (b) (4) | 14 Dec 2020 20:52:56 |
| | (b) (4) | |
| DataPoint Un-verified. | Crystal Rowell (b) (4) | 14 Dec 2020 20:52:00 |
| | (b) (4) | |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error | Crystal Rowell (b) (4) | 14 Dec 2020 20:52:00 |
| | (b) (4) | |
| User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety). | (b) (4), (b) (6) | 20 Nov 2020 22:17:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| | | |
| User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' | Crystal Rowell (b) (4) | 11 Nov 2020 17:44:43 |
| | (b) (4) | |

US3362244

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:14:58

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User entered empty. | Crystal Rowell (b) (4) (b) (4) | 11 Nov 2020 17:44:43 |

US3362244

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:14:58

[Narrative](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System). | System | 11 Nov 2020 17:48:22 |
| Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System). | System | 11 Nov 2020 17:48:22 |
| User entered 'SUBJECT HAD PICC LINE PLACED POST SURGERY, NOTE TO HAVE PAIN ON 10/19/2020 DIAGNOSED WITH DVT AND PICC LINE REMOVED, ON ANTI-COAGULANTS' reason for change: Data Entry Error | Crystal Rowell (b) (4) | 11 Nov 2020 17:48:22 |
| User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System). | (b) (4) | |
| User entered empty. | System | 11 Nov 2020 17:44:43 |
| | Crystal Rowell (b) (4) | 11 Nov 2020 17:44:43 |
| | (b) (4) | |

US3362244

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:14:58

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 11 Nov 2020 17:44:43 |

US3362244

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:14:58

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 11 Nov 2020 17:44:43 |

US3362244

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:14:58

[AEID](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:47:50 |
| | | |
| | | |

US3362244

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:14:58

[Adverse event](#)

| Audit | User | Time (GMT) |
|---|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:47:50 |
| User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Diarrhoea (excl infective), PT: Diarrhoea, LLT: Diarrhea - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 13 Mar 2021 22:36:46 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 13 Mar 2021 22:36:46 |
| Data point term sent to Coder | System | 13 Mar 2021 22:19:51 |
| User signature succeeded. | Jordan Whatley (b) (4) (b) (4) | 13 Mar 2021 22:19:50 |
| User closed query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM). | (b) (4), (b) (6) | 21 Jan 2021 16:38:06 |
| Query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' answered with 'this occurred post long term antibiotic use' (Site from DM). | Crystal Rowell (b) (4) (b) (4) | 14 Dec 2020 20:54:18 |
| User opened query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM). | (b) (4), (b) (6) | 14 Dec 2020 16:31:11 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Diarrhoea (excl infective), PT: Diarrhoea, LLT: Diarrhea - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 11 Nov 2020 22:12:37 |

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:14:58

[Adverse event](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| User coded data point as Term Coded data point by | Coder Import (b) (4) | 11 Nov 2020 22:12:37 |
| User: Coder System - version MedDRA\\23.0. | (b) (4) | |
| Data point term sent to Coder | System | 11 Nov 2020 22:11:28 |
| User entered 'diarrhea' | Crystal Rowell (b) (4) | 11 Nov 2020 22:11:02 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:14:58

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:47:50 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| | | |
| User entered 'Yes (Y)' | Crystal Rowell (b) (4) | 11 Nov 2020 22:11:02 |
| | (b) (4) | |

US3362244

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:14:58

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:47:50 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| | | |
| User entered 'No (N)' | Crystal Rowell (b) (4) | 11 Nov 2020 22:11:02 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:14:58

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:47:50 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| | | |
| User entered 'No (N)' | Crystal Rowell (b) (4) | 11 Nov 2020 22:11:02 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:14:58

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:47:50 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| | | |
| User entered '29 Oct 2020' | Crystal Rowell (b) (4) | 11 Nov 2020 22:11:02 |
| | (b) (4) | |

US3362244

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:14:58

Start time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:47:50 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| | | |
| User entered empty. | Crystal Rowell (b) (4) | 11 Nov 2020 22:11:02 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:14:58

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:47:50 |
| | | |
| User entered empty. | System | 11 Nov 2020 22:11:02 |

US3362244

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:14:58

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:47:50 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| | (b) (4) | |
| DataPoint Un-verified. | (b) (4), (b) (6) | 19 Nov 2020 22:22:39 |
| User entered 'No (N)' reason for change: Data Entry Error | | 19 Nov 2020 22:22:39 |
| DataPoint Verified. | | 19 Nov 2020 20:00:16 |
| User entered 'Yes (Y)' | Crystal Rowell (b) (4) | 11 Nov 2020 22:11:02 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:14:58

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:47:50 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| | (b) (4) | |
| User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System). | System | 19 Nov 2020 22:22:55 |
| Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System). | System | 19 Nov 2020 22:22:55 |
| User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System). | System | 19 Nov 2020 22:22:39 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 19 Nov 2020 22:22:39 |
| User entered '12 Nov 2020' reason for change: Data Entry Error | | 19 Nov 2020 22:22:39 |
| DataPoint Verified. | | 19 Nov 2020 20:00:16 |
| User entered empty. | Crystal Rowell (b) (4) | 11 Nov 2020 22:11:02 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:14:58

End time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:47:50 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| | | |
| User entered empty. | Crystal Rowell (b) (4) | 11 Nov 2020 22:11:02 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:14:58

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:47:50 |
| | | |
| User entered empty. | System | 11 Nov 2020 22:11:02 |

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:14:58

[Severity](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:47:50 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| | | |
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' | Crystal Rowell (b) (4) | 11 Nov 2020 22:11:02 |
| | (b) (4) | |

US3362244

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:14:58

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:47:50 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| | | |
| User entered 'No (N)' | Crystal Rowell (b) (4) | 11 Nov 2020 22:11:02 |
| | (b) (4) | |

US3362244

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:14:58

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:47:50 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| | | |
| User entered '0' | Crystal Rowell (b) (4) | 11 Nov 2020 22:11:02 |
| | (b) (4) | |

US3362244

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:14:58

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:47:50 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| | | |
| User entered '0' | Crystal Rowell (b) (4) | 11 Nov 2020 22:11:02 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:14:58

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:47:50 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| | | |
| User entered '0' | Crystal Rowell (b) (4) | 11 Nov 2020 22:11:02 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:14:58

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:47:50 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| | | |
| User entered empty. | Crystal Rowell (b) (4) | 11 Nov 2020 22:11:02 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:14:58

Hospital Discharge Date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:47:50 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| | | |
| User entered empty. | Crystal Rowell (b) (4) | 11 Nov 2020 22:11:02 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:14:58

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:47:50 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| | | |
| User entered empty. | Crystal Rowell (b) (4) | 11 Nov 2020 22:11:02 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:14:58

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:47:50 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| | | |
| User entered empty. | Crystal Rowell (b) (4) | 11 Nov 2020 22:11:02 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:14:58

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:47:50 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| | | |
| User entered '0' | Crystal Rowell (b) (4) | 11 Nov 2020 22:11:02 |
| | (b) (4) | |

US3362244

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:14:58

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:47:50 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| | | |
| User entered '0' | Crystal Rowell (b) (4) | 11 Nov 2020 22:11:02 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:14:58

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:47:50 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| | | |
| User entered '0' | Crystal Rowell (b) (4) | 11 Nov 2020 22:11:02 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:14:58

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:47:50 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| | | |
| User entered 'Not Related (NOT RELATED)' | Crystal Rowell (b) (4) | 11 Nov 2020 22:11:02 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:14:58

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:47:50 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| | | |
| User entered 'Not Related (NOT RELATED)' | Crystal Rowell (b) (4) | 11 Nov 2020 22:11:02 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:14:58

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:47:50 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| | | |
| User entered 'Not Applicable (NOT APPLICABLE)' | Crystal Rowell (b) (4) | 11 Nov 2020 22:11:02 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:14:58

None

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:47:50 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| | | |
| User entered '1' | Crystal Rowell (b) (4) | 11 Nov 2020 22:11:02 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:14:58

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:47:50 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| | | |
| User entered '0' | Crystal Rowell (b) (4) | 11 Nov 2020 22:11:02 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:14:58

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:47:50 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| | | |
| User entered '0' | Crystal Rowell (b) (4) | 11 Nov 2020 22:11:02 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:14:58

[Outcome](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:47:50 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| | (b) (4) | |
| DataPoint Un-verified. | (b) (4), (b) (6) | 19 Nov 2020 22:22:55 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: | | 19 Nov 2020 22:22:55 |
| Data Entry Error | | |
| DataPoint Verified. | | 19 Nov 2020 20:00:16 |
| User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' | Crystal Rowell (b) (4) | 11 Nov 2020 22:11:02 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:14:58

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:47:50 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| | | |
| User entered empty. | Crystal Rowell (b) (4) | 11 Nov 2020 22:11:02 |
| | (b) (4) | |

US3362244

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:14:58

[Narrative](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:47:50 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Nov 2020 20:00:16 |
| | | |
| User entered 'post antibiotic therapy' | Crystal Rowell (b) (4) | 11 Nov 2020 22:11:02 |
| | (b) (4) | |

US3362244

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:14:58

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:47:50 |
| | | |
| User entered '0' | System | 11 Nov 2020 22:11:02 |

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:14:58

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:47:50 |
| | | |
| User entered '1' | System | 11 Nov 2020 22:11:02 |

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:14:58

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:47:50 |
| | | |
| | | |

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Folder: Adverse Events

Form: Adverse Events (7)

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[AEID](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:47:54 |
| | | |
| | | |

US3362244

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:14:58

[Adverse event](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:47:54 |
| | | |
| User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Rashes, eruptions and exanthems NEC, PT: Rash macular, LLT: Generalized macular rash - version MedDRA\\23.0. | Coder Import (b) (4) | 13 Mar 2021 22:20:49 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) | 13 Mar 2021 22:20:49 |
| | (b) (4) | |
| Data point term sent to Coder | System | 13 Mar 2021 22:19:56 |
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| | (b) (4) | |
| User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Rashes, eruptions and exanthems NEC, PT: Rash macular, LLT: Generalized macular rash - version MedDRA\\23.0. | Coder Import (b) (4) | 27 Jan 2021 17:11:13 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) | 27 Jan 2021 17:11:13 |
| | (b) (4) | |
| User closed query 'Per DM CLR: Please review AE and please update to specify whether Rash is Urticarial or Non-urticarial. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify.' (Site from DM). | (b) (4), (b) (6) | 27 Jan 2021 16:51:03 |
| | | |
| Data point term sent to Coder | System | 26 Jan 2021 22:53:53 |
| Query 'Per DM CLR: Please review AE and please update to specify whether Rash is Urticarial or Non-urticarial. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify.' answered with 'update' (Site from DM). | Alexandra Caillouet | 26 Jan 2021 22:53:40 |
| | (b) (4) | |
| Coding entries removed. | Alexandra Caillouet | 26 Jan 2021 22:53:34 |
| | (b) (4) | |
| User entered 'MACULAR RASH Non-urticarial (GENERALIZED)' reason for change: Data Entry Error | Alexandra Caillouet | 26 Jan 2021 22:53:34 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:14:58

[Adverse event](#)

| Audit | User | Time (GMT) |
|---|----------------------------------|----------------------|
| User opened query 'Per DM CLR: Please review AE and please update to specify whether Rash is Urticarial or Non-urticarial. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify.' (Site from DM). | (b) (4), (b) (6) | 26 Jan 2021 07:27:29 |
| User closed query 'Per DM CLR - RQ: Site's response noted. However, response does not address the query. Please review and reflect the specific anatomical location (e.g., Right deltoid, etc) and if this is Urticarial or Non-Urticarial. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' (Site from DM). | (b) (4), (b) (6) | 13 Jan 2021 18:07:02 |
| User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Rashes, eruptions and exanthems NEC, PT: Rash macular, LLT: Generalized macular rash - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 13 Jan 2021 11:44:58 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 13 Jan 2021 11:44:58 |
| Data point term sent to Coder | System | 12 Jan 2021 22:26:08 |
| Query 'Per DM CLR - RQ: Site's response noted. However, response does not address the query. Please review and reflect the specific anatomical location (e.g., Right deltoid, etc) and if this is Urticarial or Non-Urticarial. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' answered with 'updated to 'generalized' (Site from DM). | Amy Thomassie (b) (4) (b) (4) | 12 Jan 2021 22:25:58 |
| Coding entries removed. | Amy Thomassie (b) (4) (b) (4) | 12 Jan 2021 22:25:14 |
| User entered 'MACULAR RASH (generalized)' reason for change: Data Entry Error | Amy Thomassie (b) (4) (b) (4) | 12 Jan 2021 22:25:14 |

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:14:58

[Adverse event](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| User opened query 'Per DM CLR - RQ: Site's response noted. However, response does not address the query. Please review and reflect the specific anatomical location (e.g., Right deltoid, etc) and if this is Urticarial or Non-Urticarial. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' (Site from DM). | (b) (4), (b) (6) | 11 Jan 2021 05:58:38 |
| User closed query 'Per DM CLR: Please review and reflect the specific type of RASH (e.g., Macular, Papular, etc) and if this is Urticarial or Non-Urticarial or if related to injection site Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' (Site from DM). | (b) (4), (b) (6) | 15 Dec 2020 18:31:40 |
| User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Rashes, eruptions and exanthems NEC, PT: Rash macular, LLT: Macular rash - version MedDRA\\23.0. | Coder Import (b) (4) | 14 Dec 2020 20:41:46 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | (b) (4) | 14 Dec 2020 20:41:46 |
| Data point term sent to Coder | System | 14 Dec 2020 20:40:59 |
| Query 'Per DM CLR: Please review and reflect the specific type of RASH (e.g., Macular, Papular, etc) and if this is Urticarial or Non-Urticarial or if related to injection site Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' answered with 'not related to injection' (Site from DM). | Crystal Rowell (b) (4) | 14 Dec 2020 20:40:25 |
| Coding entries removed. | Crystal Rowell (b) (4) | 14 Dec 2020 20:40:06 |
| User entered 'macular RASH' reason for change: Data Entry Error | Crystal Rowell (b) (4) | 14 Dec 2020 20:40:06 |

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:14:58

[Adverse event](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User opened query 'Per DM CLR: Please review and reflect the specific type of RASH (e.g., Macular, Papular, etc) and if this is Urticarial or Non-Urticarial or if related to injection site Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' (Site from DM). | (b) (4), (b) (6) | 09 Dec 2020 03:05:54 |
| User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Rashes, eruptions and exanthems NEC, PT: Rash, LLT: Rash - version MedDRA\\23.0. | Coder Import (b) (4) | 19 Nov 2020 22:47:50 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 19 Nov 2020 22:47:50 |
| Data point term sent to Coder | System | 19 Nov 2020 22:46:48 |
| User entered 'RASH' | (b) (4), (b) (6) | 19 Nov 2020 22:46:18 |

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:14:58

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:47:54 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| | (b) (4) | |
| User entered 'No (N)' | (b) (4), (b) (6) | 19 Nov 2020 22:46:18 |
| | | |

US3362244

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:14:58

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:47:54 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| | (b) (4) | |
| User entered 'No (N)' | (b) (4), (b) (6) | 19 Nov 2020 22:46:18 |
| | | |

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:14:58

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:47:54 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| | (b) (4) | |
| User entered 'No (N)' | (b) (4), (b) (6) | 19 Nov 2020 22:46:18 |
| | | |

US3362244

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:14:58

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:47:54 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| | (b) (4) | |
| User entered '11 Sep 2020' | (b) (4), (b) (6) | 19 Nov 2020 22:46:18 |
| | | |

US3362244

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:14:58

Start time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:47:54 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| | (b) (4) | |
| User entered empty. | (b) (4), (b) (6) | 19 Nov 2020 22:46:18 |
| | | |

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:14:58

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:47:54 |
| | | |
| User entered empty. | System | 19 Nov 2020 22:46:18 |

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:14:58

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:47:54 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| | (b) (4) | |
| User entered 'No (N)' | (b) (4), (b) (6) | 19 Nov 2020 22:46:18 |
| | | |

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:14:58

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:47:54 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| | (b) (4) | |
| User entered '18 Sep 2020' | (b) (4), (b) (6) | 19 Nov 2020 22:46:18 |
| | | |

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:14:58

[End time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:47:54 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| | (b) (4) | |
| User entered empty. | (b) (4), (b) (6) | 19 Nov 2020 22:46:18 |
| | | |

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:14:58

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:47:54 |
| | | |
| User entered empty. | System | 19 Nov 2020 22:46:18 |

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:14:58

[Severity](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:47:54 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| | (b) (4) | |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 20 Nov 2020 16:39:04 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 20 Nov 2020 16:39:04 |
| User entered 'Grade 1/Mild (Grade 1/Mild)' reason for change: Data Entry Error | Crystal Rowell (b) (4) | 20 Nov 2020 16:39:04 |
| | (b) (4) | |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 19 Nov 2020 22:46:18 |
| User entered empty. | (b) (4), (b) (6) | 19 Nov 2020 22:46:18 |
| | | |

US3362244

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:14:58

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:47:54 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| | (b) (4) | |
| User entered 'No (N)' | (b) (4), (b) (6) | 19 Nov 2020 22:46:18 |
| | | |

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:14:58

Death

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:47:54 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| | (b) (4) | |
| User entered '0' | (b) (4), (b) (6) | 19 Nov 2020 22:46:18 |
| | | |

US3362244

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:14:58

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:47:54 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| | (b) (4) | |
| User entered '0' | (b) (4), (b) (6) | 19 Nov 2020 22:46:18 |
| | | |

US3362244

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:14:58

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:47:54 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| | (b) (4) | |
| User entered '0' | (b) (4), (b) (6) | 19 Nov 2020 22:46:18 |
| | | |

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:14:58

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:47:54 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| | (b) (4) | |
| User entered empty. | (b) (4), (b) (6) | 19 Nov 2020 22:46:18 |
| | | |

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:14:58

Hospital Discharge Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:47:54 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| | (b) (4) | |
| User entered empty. | (b) (4), (b) (6) | 19 Nov 2020 22:46:18 |
| | | |

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:14:58

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:47:54 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| | (b) (4) | |
| User entered empty. | (b) (4), (b) (6) | 19 Nov 2020 22:46:18 |
| | | |

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:14:58

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:47:54 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| | (b) (4) | |
| User entered empty. | (b) (4), (b) (6) | 19 Nov 2020 22:46:18 |
| | | |

US3362244

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:14:58

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:47:54 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| | (b) (4) | |
| User entered '0' | (b) (4), (b) (6) | 19 Nov 2020 22:46:18 |
| | | |

US3362244

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:14:58

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:47:54 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| | (b) (4) | |
| User entered '0' | (b) (4), (b) (6) | 19 Nov 2020 22:46:18 |
| | | |

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:14:58

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:47:54 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| | (b) (4) | |
| User entered '0' | (b) (4), (b) (6) | 19 Nov 2020 22:46:18 |
| | | |

US3362244

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:14:58

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:47:54 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| | (b) (4) | |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 20 Nov 2020 16:39:04 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 20 Nov 2020 16:39:04 |
| User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error | Crystal Rowell (b) (4) | 20 Nov 2020 16:39:04 |
| | (b) (4) | |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 19 Nov 2020 22:46:18 |
| User entered empty. | (b) (4), (b) (6) | 19 Nov 2020 22:46:18 |
| | | |

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:14:58

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:47:54 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| | (b) (4) | |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 20 Nov 2020 16:39:04 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 20 Nov 2020 16:39:04 |
| User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error | Crystal Rowell (b) (4) | 20 Nov 2020 16:39:04 |
| | (b) (4) | |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 19 Nov 2020 22:46:18 |
| User entered empty. | (b) (4), (b) (6) | 19 Nov 2020 22:46:18 |
| | | |

US3362244

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:14:58

Action taken with investigational product

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:47:54 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| | (b) (4) | |
| User closed query 'Per CDM-Action taken with investigational product is recorded as 'none',however,per ccg page 34 Action taken with investigational product is expected to be 'Not Applicable' if If adverse event started AFTER last dose.Kindly consider to verify and update data appropriately else clarify.' (Site from DM). | (b) (4), (b) (6) | 15 Dec 2020 18:31:57 |
| Query 'Per CDM-Action taken with investigational product is recorded as 'none',however,per ccg page 34 Action taken with investigational product is expected to be 'Not Applicable' if If adverse event started AFTER last dose.Kindly consider to verify and update data appropriately else clarify.' answered with 'updated ' (Site from DM). | Crystal Rowell (b) (4) | 14 Dec 2020 20:40:37 |
| | (b) (4) | |
| User opened query 'Per CDM-Action taken with investigational product is recorded as 'none',however,per ccg page 34 Action taken with investigational product is expected to be 'Not Applicable' if If adverse event started AFTER last dose.Kindly consider to verify and update data appropriately else clarify.' (Site from DM). | (b) (4), (b) (6) | 26 Nov 2020 08:12:43 |
| | | |
| User entered 'Not Applicable (NOT APPLICABLE)' | (b) (4), (b) (6) | 19 Nov 2020 22:46:18 |
| | | |

US3362244

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:14:58

None

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:47:54 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| | (b) (4) | |
| User entered 'I' | (b) (4), (b) (6) | 19 Nov 2020 22:46:18 |
| | | |

US3362244

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:14:58

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:47:54 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| | (b) (4) | |
| User entered '0' | (b) (4), (b) (6) | 19 Nov 2020 22:46:18 |
| | | |

US3362244

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:14:58

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:47:54 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| | (b) (4) | |
| User entered '0' | (b) (4), (b) (6) | 19 Nov 2020 22:46:18 |
| | | |

US3362244

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:14:58

[Outcome](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:47:54 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| | (b) (4) | |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | (b) (4), (b) (6) | 19 Nov 2020 22:46:18 |
| | | |

US3362244

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:14:58

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:47:54 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| | (b) (4) | |
| User entered empty. | (b) (4), (b) (6) | 19 Nov 2020 22:46:18 |
| | | |

US3362244

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:14:58

[Narrative](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:47:54 |
| | | |
| User signature succeeded. | Jordan Whatley (b) (4) | 13 Mar 2021 22:19:50 |
| | (b) (4) | |
| User entered empty. | (b) (4), (b) (6) | 19 Nov 2020 22:46:18 |
| | | |

US3362244

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:14:58

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:47:54 |
| | | |
| User entered '0' | System | 19 Nov 2020 22:46:18 |

US3362244

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:14:58

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:47:54 |
| | | |
| User entered '0' | System | 19 Nov 2020 22:46:18 |

US3362244

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:14:58

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:47:54 |
| | | |
| | | |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 06:00:37 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User closed query 'Per ETRTR: According to SAE "Worsening of Anterior Left Pelvic Ring Non-union" page, medication was dosed. Please add Medication dosing details for SAE "Worsening of Anterior Left Pelvic Ring Non-union" within ConMeds page, thanks.' (Site from CRA). | (b) (4) (b) (4), (b) (6) | 15 Nov 2020 21:01:22 |
| Query 'Per ETRTR: According to SAE "Worsening of Anterior Left Pelvic Ring Non-union" page, medication was dosed. Please add Medication dosing details for SAE "Worsening of Anterior Left Pelvic Ring Non-union" within ConMeds page, thanks.' answered with 'this has been updated' (Site from CRA). | Crystal Rowell (b) (4) (b) (4) | 12 Nov 2020 15:27:01 |
| User opened query 'Per ETRTR: According to SAE "Worsening of Anterior Left Pelvic Ring Non-union" page, medication was dosed. Please add Medication dosing details for SAE "Worsening of Anterior Left Pelvic Ring Non-union" within ConMeds page, thanks.' (Site from CRA). | (b) (4), (b) (6) | 05 Nov 2020 15:33:54 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 25 Aug 2020 15:14:38 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:14:58

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|--|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: DRUGS FOR TREATMENT OF BONE DISEASES, ATC: DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION, ATC: BISPHOSPHONATES, PRODUCT: ALENDRONATE SODIUM, PRODUCTSYNONYM: ALENDRONATE - version WHODrug-Global-B3\\202003. | (b) (4) Coder Import (b) (4) (b) (4) | 25 Aug 2020 15:16:35 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 25 Aug 2020 15:16:35 |
| Data point term sent to Coder | System | 25 Aug 2020 15:15:23 |
| User entered 'Alendronate' | (b) (4), (b) (6) | 25 Aug 2020 15:15:22 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:14:58

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 25 Aug 2020 15:15:22 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:14:58

[Indication](#)

| Audit | User | Time (GMT) |
|-----------------------------|-----------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'Osteoporosis' | (b) (4) (b) (4), (b) (6) | 25 Aug 2020 15:15:22 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:14:58

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered '70' | (b) (4) (b) (4), (b) (6) | 25 Aug 2020 15:15:22 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:14:58

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'mg (mg)' | (b) (4) (b) (4), (b) (6) | 25 Aug 2020 15:15:22 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:14:58

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 25 Aug 2020 15:15:22 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:14:58

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'every week (QS)' | (b) (4) (b) (4), (b) (6) | 25 Aug 2020 15:15:22 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:14:58

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 25 Aug 2020 15:15:22 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:14:58

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'Oral (ORAL)' | (b) (4) (b) (4), (b) (6) | 25 Aug 2020 15:15:22 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:14:58

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 25 Aug 2020 15:15:22 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'un UNK 2019' | (b) (4) (b) (4), (b) (6) | 25 Aug 2020 15:15:22 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:14:58

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 25 Aug 2020 15:15:22 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:14:58

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 25 Aug 2020 15:15:22 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:14:58

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 25 Aug 2020 15:15:22 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:14:58

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 25 Aug 2020 15:15:22 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:14:58

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 25 Aug 2020 15:15:22 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:14:58

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 25 Aug 2020 15:15:22 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:14:58

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '803 (803)' | System | 25 Aug 2020 15:15:22 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:14:58

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:59 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003. | (b) (4) Coder Import (b) (4) (b) (4) | 25 Aug 2020 15:19:34 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 25 Aug 2020 15:19:34 |
| Data point term sent to Coder | System | 25 Aug 2020 15:18:28 |
| User entered 'Atorvastatin' | (b) (4), (b) (6) | 25 Aug 2020 15:17:39 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:14:58

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:59 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 25 Aug 2020 15:17:39 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:14:58

[Indication](#)

| Audit | User | Time (GMT) |
|-------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:59 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'hyperlipidemia' | (b) (4), (b) (6) | 25 Aug 2020 15:17:39 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:14:58

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:59 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered '80' | (b) (4), (b) (6) | 25 Aug 2020 15:17:39 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:14:58

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:59 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'mg (mg)' | (b) (4) (b) (4), (b) (6) | 25 Aug 2020 15:17:39 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:14:58

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:59 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 25 Aug 2020 15:17:39 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:14:58

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:59 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'once daily (QD)' | (b) (4) (b) (4), (b) (6) | 25 Aug 2020 15:17:39 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:14:58

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:59 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 25 Aug 2020 15:17:39 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:14:58

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:59 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'Oral (ORAL)' | (b) (4) (b) (4), (b) (6) | 25 Aug 2020 15:17:39 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:14:58

[If route of administration is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:59 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered empty. | (b) (4), (b) (6) | 25 Aug 2020 15:17:39 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:14:58

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:59 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition (MH#2=2015). Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 08 Oct 2020 10:26:50 |
| Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition (MH#2=2015). Please review and reconcile Con Med and MH start dates as appropriate.' answered with 'updated' (Site from DM). | Crystal Rowell (b) (4) (b) (4) | 02 Oct 2020 19:40:41 |
| User entered 'UN UNK 2015' reason for change: Data Entry Error | Crystal Rowell (b) (4) (b) (4) | 02 Oct 2020 19:40:35 |
| User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition (MH#2=2015). Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM). | (b) (4), (b) (6) | 29 Sep 2020 09:59:56 |
| User entered 'un UNK 2013' | (b) (4), (b) (6) | 25 Aug 2020 15:17:39 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:14:58

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:59 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered '0' | (b) (4), (b) (6) | 25 Aug 2020 15:17:39 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:14:58

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:59 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'No (N)' reason for change: Data Entry Error | Crystal Rowell (b) (4) | 12 Nov 2020 20:50:13 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 25 Aug 2020 15:17:39 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:14:58

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:59 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered '3 Nov 2020' reason for change: Data Entry Error | (b) (4) | 12 Nov 2020 20:50:13 |
| User entered empty. | Crystal Rowell (b) (4) | 25 Aug 2020 15:17:39 |
| | (b) (4), (b) (6) | |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:14:58

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:59 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 25 Aug 2020 15:17:39 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:14:58

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:59 |
| User entered '1' | System | 25 Aug 2020 15:17:39 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:14:58

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:59 |
| User entered '1' | System | 25 Aug 2020 15:17:39 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:14:58

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:59 |
| User entered '804 (804)' | System | 25 Aug 2020 15:17:39 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:14:58

Name of Medication

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL ARTHRITIS - version WHODrug-Global-B3\\202003. | (b) (4) Coder Import (b) (4) | 30 Oct 2020 16:33:55 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 30 Oct 2020 16:33:55 |
| Data point term sent to Coder | System | 30 Oct 2020 16:33:18 |
| Coding entries removed. | (b) (4), (b) (6) | 30 Oct 2020 16:33:04 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL ARTHRITIS - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 01 Sep 2020 22:23:38 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 01 Sep 2020 22:23:38 |
| Data point term sent to Coder | System | 01 Sep 2020 22:22:19 |
| User entered 'tylenol arthritis' | Crystal Rowell (b) (4) | 01 Sep 2020 22:21:59 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:14:58

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| | (b) (4) | |
| User entered 'No (N)' | Crystal Rowell (b) (4) | 01 Sep 2020 22:21:59 |
| | (b) (4) | |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:14:58

[Indication](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User closed query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis). Review and update indication as appropriate and ensure update is reconciled with any corresponding MH/AE entries, if applicable. '(Site from DM). | (b) (4) (b) (4), (b) (6) | 04 Nov 2020 06:48:23 |
| Query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis). Review and update indication as appropriate and ensure update is reconciled with any corresponding MH/AE entries, if applicable. ' answered with 'UPDATED' (Site from DM). | (b) (4), (b) (6) | 30 Oct 2020 16:33:17 |
| User entered 'OSTEOARTHRITIS' reason for change: Data Entry Error | (b) (4), (b) (6) | 30 Oct 2020 16:33:04 |
| User opened query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis). Review and update indication as appropriate and ensure update is reconciled with any corresponding MH/AE entries, if applicable. '(Site from DM). | (b) (4), (b) (6) | 26 Oct 2020 09:10:40 |
| User entered 'arthritis' | Crystal Rowell (b) (4) (b) (4) | 01 Sep 2020 22:21:59 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:14:58

[Dose per administration](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM). | (b) (4) (b) (4), (b) (6) | 18 Jan 2021 16:03:43 |
| Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' answered with 'updated' (Site from DM). | Amy Thomassie (b) (4) (b) (4) | 16 Jan 2021 15:30:31 |
| User entered '650' reason for change: Data Entry Error | Amy Thomassie (b) (4) (b) (4) | 16 Jan 2021 15:30:24 |
| User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM). | (b) (4), (b) (6) | 15 Jan 2021 21:16:48 |
| User entered '1' | Crystal Rowell (b) (4) (b) (4) | 01 Sep 2020 22:21:59 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:14:58

[Dose unit](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| | (b) (4) | |
| User entered 'mg (mg)' reason for change: Data Entry Error | Amy Thomassie (b) (4) | 16 Jan 2021 15:30:24 |
| | (b) (4) | |
| User entered 'tablet (TABLET)' | Crystal Rowell (b) (4) | 01 Sep 2020 22:21:59 |
| | (b) (4) | |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:14:58

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| | (b) (4) | |
| User entered empty. | Crystal Rowell (b) (4) | 01 Sep 2020 22:21:59 |
| | (b) (4) | |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:14:58

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| | (b) (4) | |
| User entered 'as needed (PRN)' | Crystal Rowell (b) (4) | 01 Sep 2020 22:21:59 |
| | (b) (4) | |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:14:58

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| | (b) (4) | |
| User entered empty. | Crystal Rowell (b) (4) | 01 Sep 2020 22:21:59 |
| | (b) (4) | |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:14:58

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'Oral (ORAL)' | (b) (4) Crystal Rowell (b) (4) | 01 Sep 2020 22:21:59 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:14:58

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| | (b) (4) | |
| User entered empty. | Crystal Rowell (b) (4) | 01 Sep 2020 22:21:59 |
| | (b) (4) | |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:14:58

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| | (b) (4) | |
| User entered 'UN UNK 2010' | Crystal Rowell (b) (4) | 01 Sep 2020 22:21:59 |
| | (b) (4) | |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:14:58

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| | (b) (4) | |
| User entered '0' | Crystal Rowell (b) (4) | 01 Sep 2020 22:21:59 |
| | (b) (4) | |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:14:58

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Crystal Rowell (b) (4) | 01 Sep 2020 22:21:59 |
| | (b) (4) | |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:14:58

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| | (b) (4) | |
| User entered empty. | Crystal Rowell (b) (4) | 01 Sep 2020 22:21:59 |
| | (b) (4) | |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:14:58

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| | (b) (4) | |
| User entered 'No (N)' | Crystal Rowell (b) (4) | 01 Sep 2020 22:21:59 |
| | (b) (4) | |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:14:58

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 01 Sep 2020 22:21:59 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:14:58

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 01 Sep 2020 22:21:59 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:14:58

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 01 Sep 2020 22:21:59 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:14:58

Name of Medication

| Audit | User | Time (GMT) |
|---|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 02:59:58 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening OSTEOARTHRITIS should be recorded, and update con med indication or provide clarification. ' (Site from DM). | (b) (4) (b) (4), (b) (6) | 18 Jan 2021 16:04:01 |
| Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening OSTEOARTHRITIS should be recorded, and update con med indication or provide clarification. ' answered with 'condition did not worsen' (Site from DM). | Amy Thomassie (b) (4) (b) (4) | 16 Jan 2021 15:45:05 |
| User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening OSTEOARTHRITIS should be recorded, and update con med indication or provide clarification. ' (Site from DM). | (b) (4), (b) (6) | 15 Jan 2021 21:20:37 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL EXTRA STRENGTH - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 30 Oct 2020 16:36:54 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 30 Oct 2020 16:36:54 |
| Data point term sent to Coder | System | 30 Oct 2020 16:36:20 |
| Coding entries removed. | (b) (4), (b) (6) | 30 Oct 2020 16:35:20 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:14:58

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL EXTRA STRENGTH - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 14 Sep 2020 17:09:45 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 14 Sep 2020 17:09:45 |
| Data point term sent to Coder | System | 14 Sep 2020 17:08:38 |
| User entered 'Tylenol Extra Strength' | (b) (4), (b) (6) | 14 Sep 2020 17:07:39 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:14:58

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 02:59:58 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 14 Sep 2020 17:07:39 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:14:58

[Indication](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 02:59:58 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User closed query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis). Review and update indication as appropriate and ensure update is reconciled with any corresponding MH/AE entries, if applicable. ' (Site from DM). | (b) (4) (b) (4), (b) (6) | 04 Nov 2020 06:50:06 |
| Query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis). Review and update indication as appropriate and ensure update is reconciled with any corresponding MH/AE entries, if applicable. ' answered with 'updated' (Site from DM). | (b) (4), (b) (6) | 30 Oct 2020 16:35:28 |
| User entered 'OSTEOARTHRITIS' reason for change: Data Entry Error | (b) (4), (b) (6) | 30 Oct 2020 16:35:20 |
| User opened query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis). Review and update indication as appropriate and ensure update is reconciled with any corresponding MH/AE entries, if applicable. ' (Site from DM). | (b) (4), (b) (6) | 26 Oct 2020 09:11:10 |
| User entered 'arthritis' | (b) (4), (b) (6) | 14 Sep 2020 17:07:39 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:14:58

[Dose per administration](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 02:59:58 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User closed query 'Per DM CLR: Previous response indicate data was updated; however, the dose recorded is still not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM). | (b) (4) | |
| Query 'Per DM CLR: Previous response indicate data was updated; however, the dose recorded is still not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'updated' (Site from DM). | (b) (4), (b) (6) | 18 Jan 2021 16:04:04 |
| User entered '500' reason for change: Data Entry Error | Amy Thomassie (b) (4) | 16 Jan 2021 15:31:35 |
| User opened query 'Per DM CLR: Previous response indicate data was updated; however, the dose recorded is still not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM). | (b) (4) | |
| User closed query 'Per CDM-CLR RQ: As per previous response 'updated', However update is not obvious. Please review the dose recorded and update as appropriately as requested per previous query. Thank you' (Site from DM). | (b) (4), (b) (6) | 15 Jan 2021 21:20:12 |
| Query 'Per CDM-CLR RQ: As per previous response 'updated', However update is not obvious. Please review the dose recorded and update as appropriately as requested per previous query. Thank you' answered with 'updated' (Site from DM). | Amy Thomassie (b) (4) | 16 Jan 2021 15:31:15 |
| User entered '650' reason for change: Data Entry Error | (b) (4) | |
| User closed query 'Per CDM-CLR RQ: As per previous response 'updated', However update is not obvious. Please review the dose recorded and update as appropriately as requested per previous query. Thank you' (Site from DM). | (b) (4), (b) (6) | 10 Dec 2020 18:05:40 |
| Query 'Per CDM-CLR RQ: As per previous response 'updated', However update is not obvious. Please review the dose recorded and update as appropriately as requested per previous query. Thank you' answered with 'updated' (Site from DM). | (b) (4), (b) (6) | |
| User entered '650' reason for change: Data Entry Error | Alexandra Caillouet (b) (4) | 09 Dec 2020 20:46:28 |
| User opened query 'Per CDM-CLR RQ: As per previous response 'updated', However update is not obvious. Please review the dose recorded and update as appropriately as requested per previous query. Thank you' (Site from DM). | (b) (4) | |
| User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM). | Alexandra Caillouet (b) (4) | 09 Dec 2020 20:46:23 |
| User opened query 'Per CDM-CLR RQ: As per previous response 'updated', However update is not obvious. Please review the dose recorded and update as appropriately as requested per previous query. Thank you' (Site from DM). | (b) (4), (b) (6) | 03 Dec 2020 09:13:23 |
| User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM). | (b) (4), (b) (6) | 03 Dec 2020 09:13:23 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:14:58

[Dose per administration](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'updated' (Site from DM). | (b) (4), (b) (6) | 02 Dec 2020 19:50:02 |
| User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM). | (b) (4), (b) (6) | 30 Nov 2020 19:34:40 |
| User entered '325' | (b) (4), (b) (6) | 14 Sep 2020 17:07:39 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:14:58

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 02:59:58 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'mg (mg)' | (b) (4) (b) (4), (b) (6) | 14 Sep 2020 17:07:39 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:14:58

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 02:59:58 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 14 Sep 2020 17:07:39 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:14:58

[Frequency](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 02:59:58 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'as needed (PRN)' reason for change: Data Entry Error | (b) (4) (b) (4), (b) (6) | 02 Dec 2020 19:49:53 |
| User entered 'once daily (QD)' | (b) (4), (b) (6) | 14 Sep 2020 17:07:39 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:14:58

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 02:59:58 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 14 Sep 2020 17:07:39 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:14:58

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 02:59:58 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'Oral (ORAL)' | (b) (4) (b) (4), (b) (6) | 14 Sep 2020 17:07:39 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:14:58

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 02:59:58 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 14 Sep 2020 17:07:39 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 02:59:58 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered '25 Aug 2020' | (b) (4) (b) (4), (b) (6) | 14 Sep 2020 17:07:39 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:14:58

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 02:59:58 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 14 Sep 2020 17:07:39 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:14:58

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 02:59:58 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 14 Sep 2020 17:07:39 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:14:58

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 02:59:58 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered '27 Aug 2020' | (b) (4) (b) (4), (b) (6) | 14 Sep 2020 17:07:39 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:14:58

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 02:59:58 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User closed query 'Per DM CLR: 'Was this medication taken for solicited event' = Yes, however this indication is not listed as one of Solicited events. Please review if response should be updated. Otherwise, please provide clarification.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 09 Oct 2020 10:41:03 |
| Query 'Per DM CLR: 'Was this medication taken for solicited event' = Yes, however this indication is not listed as one of Solicited events. Please review if response should be updated. Otherwise, please provide clarification.' answered with 'entry error' (Site from DM). | (b) (4), (b) (6) | 07 Oct 2020 20:42:02 |
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4), (b) (6) | 07 Oct 2020 20:41:50 |
| User opened query 'Per DM CLR: 'Was this medication taken for solicited event' = Yes, however this indication is not listed as one of Solicited events. Please review if response should be updated. Otherwise, please provide clarification.' (Site from DM). | (b) (4), (b) (6) | 03 Oct 2020 14:35:08 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 14 Sep 2020 17:07:39 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:14:58

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 02:59:58 |
| User entered empty. | System | 02 Dec 2020 19:49:53 |
| User entered '1' | System | 14 Sep 2020 17:07:39 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:14:58

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 02:59:58 |
| User entered empty. | System | 02 Dec 2020 19:49:53 |
| User entered '1' | System | 14 Sep 2020 17:07:39 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:14:58

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 02:59:58 |
| User entered empty. | System | 02 Dec 2020 19:49:53 |
| User entered '804 (804)' | System | 14 Sep 2020 17:07:39 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:14:58

Name of Medication

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:05 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 09 Dec 2020 20:50:43 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 09 Dec 2020 20:50:43 |
| Data point term sent to Coder | System | 09 Dec 2020 20:49:19 |
| Coding entries removed. | Alexandra Caillouet | 09 Dec 2020 20:48:20 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 02 Oct 2020 20:03:46 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 02 Oct 2020 20:03:46 |
| Data point term sent to Coder | System | 02 Oct 2020 20:02:38 |
| User entered 'Tramadol' | (b) (4), (b) (6) | 02 Oct 2020 20:02:32 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:14:58

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:05 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 02 Oct 2020 20:02:32 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:14:58

[Indication](#)

| Audit | User | Time (GMT) |
|---|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:05 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User closed query 'Per DM CLR: Please update the indication to reflect the location/type of ARTHRITIS. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM). | (b) (4) (b) (4), (b) (6) | 10 Dec 2020 18:04:36 |
| Query 'Per DM CLR: Please update the indication to reflect the location/type of ARTHRITIS. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'MH updated to osteoarthritis of bilateral hands.' (Site from DM). | Alexandra Caillouet (b) (4) | 09 Dec 2020 20:48:25 |
| User entered 'osteoarthritis' reason for change: Data Entry Error | Alexandra Caillouet (b) (4) | 09 Dec 2020 20:48:20 |
| User opened query 'Per DM CLR: Please update the indication to reflect the location/type of ARTHRITIS. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM). | (b) (4), (b) (6) | 30 Nov 2020 19:37:17 |
| User entered 'arthritis' | (b) (4), (b) (6) | 02 Oct 2020 20:02:32 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:14:58

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:05 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered '25' | (b) (4) (b) (4), (b) (6) | 02 Oct 2020 20:02:32 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:14:58

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:05 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'mg (mg)' | (b) (4) (b) (4), (b) (6) | 02 Oct 2020 20:02:32 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:14:58

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:05 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 02 Oct 2020 20:02:32 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:14:58

[Frequency](#)

| Audit | User | Time (GMT) |
|------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:05 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'other (OTHER)' | (b) (4) (b) (4), (b) (6) | 02 Oct 2020 20:02:32 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:14:58

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|-------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:05 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'every 12 hours' | (b) (4) (b) (4), (b) (6) | 02 Oct 2020 20:02:32 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:14:58

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:05 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'Oral (ORAL)' | (b) (4) (b) (4), (b) (6) | 02 Oct 2020 20:02:32 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:14:58

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:05 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 02 Oct 2020 20:02:32 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:14:58

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:05 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'UN Feb 2020' | (b) (4) (b) (4), (b) (6) | 02 Oct 2020 20:02:32 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:14:58

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:05 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 02 Oct 2020 20:02:32 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:14:58

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:05 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'No (N)' reason for change: Data Entry Error | Crystal Rowell (b) (4) | 12 Nov 2020 20:46:19 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 02 Oct 2020 20:02:32 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:14:58

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:05 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered '3 Nov 2020' reason for change: Data Entry Error | Crystal Rowell (b) (4) | 12 Nov 2020 20:46:19 |
| User entered empty. | (b) (4), (b) (6) | 02 Oct 2020 20:02:32 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:14:58

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:05 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'No (N)' reason for change: Data Entry Error | Crystal Rowell (b) (4) | 12 Nov 2020 20:46:24 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 02 Oct 2020 20:02:32 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:14:58

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:05 |
| User entered empty. | System | 02 Oct 2020 20:02:32 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:14:58

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:05 |
| User entered empty. | System | 02 Oct 2020 20:02:32 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:14:58

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:05 |
| User entered empty. | System | 02 Oct 2020 20:02:32 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:14:58

Name of Medication

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: HYDROCODONE/ACETAMINOPHEN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 11 Nov 2020 17:42:35 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 11 Nov 2020 17:42:35 |
| Data point term sent to Coder | System | 11 Nov 2020 17:26:55 |
| User entered 'HYDROCODONE/ACETAMINOPHEN' reason for change: Data Entry Error | Crystal Rowell (b) (4) | 11 Nov 2020 17:26:07 |
| Data point term sent to Coder | System | 11 Nov 2020 17:25:53 |
| Coding entries removed. | Crystal Rowell (b) (4) | 11 Nov 2020 17:25:00 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: HYDROCODONE/ACETAMINOPHEN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 03 Oct 2020 07:06:45 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 03 Oct 2020 07:06:45 |
| Data point term sent to Coder | System | 02 Oct 2020 20:41:55 |
| User entered 'hydrocodone/actetamenophen' | (b) (4), (b) (6) | 02 Oct 2020 20:41:43 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:14:58

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 02 Oct 2020 20:41:43 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:14:58

[Indication](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'PAIN SECONDARY worsening of anterior left pelvic ring non-union' reason for change: Data Entry Error | (b) (4) Crystal Rowell (b) (4) | 11 Nov 2020 17:25:00 |
| User entered 'pain secondary to hip fracture' | (b) (4), (b) (6) | 02 Oct 2020 20:41:43 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:14:58

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered '7.5/325' | (b) (4) (b) (4), (b) (6) | 02 Oct 2020 20:41:43 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:14:58

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'mg (mg)' | (b) (4) (b) (4), (b) (6) | 02 Oct 2020 20:41:43 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:14:58

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 02 Oct 2020 20:41:43 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:14:58

[Frequency](#)

| Audit | User | Time (GMT) |
|---------------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'four times daily (QID)' | (b) (4) (b) (4), (b) (6) | 02 Oct 2020 20:41:43 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:14:58

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 02 Oct 2020 20:41:43 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:14:58

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'Oral (ORAL)' | (b) (4) (b) (4), (b) (6) | 02 Oct 2020 20:41:43 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:14:58

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 02 Oct 2020 20:41:43 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered '22 Sep 2020' | (b) (4) (b) (4), (b) (6) | 02 Oct 2020 20:41:43 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:14:58

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 02 Oct 2020 20:41:43 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:14:58

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'No (N)' reason for change: Data Entry Error | Crystal Rowell (b) (4) | 12 Nov 2020 20:45:10 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 02 Oct 2020 20:41:43 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:14:58

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered '3 Nov 2020' reason for change: Data Entry Error | Crystal Rowell (b) (4) | 12 Nov 2020 20:45:10 |
| User entered empty. | (b) (4), (b) (6) | 02 Oct 2020 20:41:43 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:14:58

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:11 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 02 Oct 2020 20:41:43 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:14:58

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:11 |
| User entered '4' | System | 02 Oct 2020 20:41:43 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:14:58

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:11 |
| User entered '1' | System | 02 Oct 2020 20:41:43 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:14:58

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:11 |
| User entered '804 (804)' | System | 02 Oct 2020 20:41:43 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:14:58

Name of Medication

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:19 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: METHYLPREDNISOLONE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 15 Nov 2020 08:26:42 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 15 Nov 2020 08:26:42 |
| Data point term sent to Coder | System | 12 Nov 2020 20:44:54 |
| Coding entries removed. | Crystal Rowell (b) (4) | 12 Nov 2020 20:44:03 |
| User entered 'METHYLPREDNISOLONE' reason for change: Data Entry Error | Crystal Rowell (b) (4) | 12 Nov 2020 20:44:03 |
| User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: METHYLPREDNISOLONE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 03 Oct 2020 06:50:38 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 03 Oct 2020 06:50:38 |
| Data point term sent to Coder | System | 02 Oct 2020 20:43:58 |
| User entered 'methylprednisilone' | (b) (4), (b) (6) | 02 Oct 2020 20:43:54 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:14:58

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:19 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 02 Oct 2020 20:43:54 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:14:58

[Indication](#)

| Audit | User | Time (GMT) |
|-----------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:19 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'pain/ hip fracture' | (b) (4) (b) (4), (b) (6) | 02 Oct 2020 20:43:54 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:14:58

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:19 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered '4' | (b) (4) (b) (4), (b) (6) | 02 Oct 2020 20:43:54 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:14:58

[Dose unit](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:19 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'mg (mg)' reason for change: Data Entry Error | (b) (4) | |
| | Alexandra Caillouet | 09 Dec 2020 20:49:48 |
| | (b) (4) | |
| User closed query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System). | System | 02 Oct 2020 20:48:24 |
| User entered 'Other (OTHER)' reason for change: Data Entry Error | (b) (4), (b) (6) | 02 Oct 2020 20:48:24 |
| | | |
| User opened query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System). | System | 02 Oct 2020 20:43:54 |
| User entered 'mg (mg)' | (b) (4), (b) (6) | 02 Oct 2020 20:43:54 |
| | | |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:14:58

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:19 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User closed query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM). | (b) (4) (b) (4), (b) (6) | 10 Dec 2020 18:04:54 |
| Query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' answered with 'updated' (Site from DM). | Alexandra Caillouet (b) (4) | 09 Dec 2020 20:50:25 |
| User entered empty; reason for change Data Entry Error | Alexandra Caillouet (b) (4) | 09 Dec 2020 20:49:48 |
| User opened query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM). | (b) (4), (b) (6) | 30 Nov 2020 19:39:34 |
| Query 'METHYLPREDNISILONE ' canceled (Site from DM). | (b) (4), (b) (6) | 30 Nov 2020 19:39:31 |
| User opened query 'METHYLPREDNISILONE ' (Site from DM). | | 30 Nov 2020 19:39:24 |
| User entered 'dose pack' | | 02 Oct 2020 20:43:54 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:14:58

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:19 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'once daily (QD)' | (b) (4) (b) (4), (b) (6) | 02 Oct 2020 20:43:54 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:14:58

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:19 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 02 Oct 2020 20:43:54 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:14:58

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:19 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'Oral (ORAL)' | (b) (4) (b) (4), (b) (6) | 02 Oct 2020 20:43:54 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:14:58

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:19 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 02 Oct 2020 20:43:54 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:14:58

Start date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:19 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered '9 Sep 2020' | (b) (4) (b) (4), (b) (6) | 02 Oct 2020 20:43:54 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:14:58

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:19 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 02 Oct 2020 20:43:54 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:14:58

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:19 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 02 Oct 2020 20:43:54 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:14:58

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:19 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered '13 Sep 2020' | (b) (4) (b) (4), (b) (6) | 02 Oct 2020 20:43:54 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:14:58

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:19 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 02 Oct 2020 20:43:54 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:14:58

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:19 |
| User entered '1' | System | 02 Oct 2020 20:43:54 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:14:58

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:19 |
| User entered '1' | System | 02 Oct 2020 20:43:54 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:14:58

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:19 |
| User entered '804 (804)' | System | 02 Oct 2020 20:43:54 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:14:58

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:24 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| 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) | 15 Nov 2020 06:15:39 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 15 Nov 2020 06:15:39 |
| Data point term sent to Coder | System | 11 Nov 2020 17:24:53 |
| Coding entries removed. | Crystal Rowell (b) (4) | 11 Nov 2020 17:24:31 |
| 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) | 02 Oct 2020 20:52:49 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 02 Oct 2020 20:52:49 |
| Data point term sent to Coder | System | 02 Oct 2020 20:46:00 |
| User entered 'gabapentin' | (b) (4), (b) (6) | 02 Oct 2020 20:45:18 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:14:58

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:24 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 02 Oct 2020 20:45:18 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:14:58

[Indication](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:24 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'worsening of anterior left pelvic ring non-union' reason for change: Data Entry Error | (b) (4) | 11 Nov 2020 17:24:31 |
| User entered 'hip pain/fracture' | Crystal Rowell (b) (4) | 02 Oct 2020 20:45:18 |
| | (b) (4), (b) (6) | |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:14:58

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:24 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered '100' | (b) (4) (b) (4), (b) (6) | 02 Oct 2020 20:45:18 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:14:58

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:24 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'mg (mg)' | (b) (4) (b) (4), (b) (6) | 02 Oct 2020 20:45:18 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:14:58

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:24 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 02 Oct 2020 20:45:18 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:14:58

[Frequency](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:24 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'three times daily (TID)' | (b) (4) (b) (4), (b) (6) | 02 Oct 2020 20:45:18 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:14:58

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:24 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 02 Oct 2020 20:45:18 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:14:58

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:24 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'Oral (ORAL)' | (b) (4) (b) (4), (b) (6) | 02 Oct 2020 20:45:18 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:14:58

[If route of administration is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:24 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 02 Oct 2020 20:45:18 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:24 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered '9 Sep 2020' | (b) (4) (b) (4), (b) (6) | 02 Oct 2020 20:45:18 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:14:58

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:24 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 02 Oct 2020 20:45:18 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:14:58

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:24 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'No (N)' reason for change: Data Entry Error | Crystal Rowell (b) (4) | 12 Nov 2020 20:42:00 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 02 Oct 2020 20:45:18 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:14:58

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:24 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered '3 Nov 2020' reason for change: Data Entry Error | Crystal Rowell (b) (4) | 12 Nov 2020 20:42:00 |
| User entered empty. | (b) (4), (b) (6) | 02 Oct 2020 20:45:18 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:14:58

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:24 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 02 Oct 2020 20:45:18 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:14:58

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:24 |
| User entered '3' | System | 02 Oct 2020 20:45:18 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:14:58

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:24 |
| User entered '1' | System | 02 Oct 2020 20:45:18 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:14:58

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:24 |
| User entered '804 (804)' | System | 02 Oct 2020 20:45:18 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:14:58

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:35 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: CONTACT LAXATIVES, PRODUCT: BISACODYL, PRODUCTSYNONYM: DULCOLAX [BISACODYL] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 06 Oct 2020 14:37:18 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 06 Oct 2020 14:37:18 |
| Data point term sent to Coder | System | 02 Oct 2020 20:47:02 |
| User entered 'dulcolax' | (b) (4), (b) (6) | 02 Oct 2020 20:46:49 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:14:58

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:35 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User closed query 'Per DM CLR: The indication signifies PREVENTION. However, the response in this field reflects otherwise, Please review and update as appropriate. Else, provide justification.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 18 Jan 2021 16:04:29 |
| Query 'Per DM CLR: The indication signifies PREVENTION. However, the response in this field reflects otherwise, Please review and update as appropriate. Else, provide justification.' answered with 'updated' (Site from DM). | Amy Thomassie (b) (4) (b) (4) | 16 Jan 2021 15:45:56 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Amy Thomassie (b) (4) (b) (4) | 16 Jan 2021 15:45:46 |
| User opened query 'Per DM CLR: The indication signifies PREVENTION. However, the response in this field reflects otherwise, Please review and update as appropriate. Else, provide justification.' (Site from DM). | (b) (4), (b) (6) | 15 Jan 2021 21:23:43 |
| User entered 'No (N)' | (b) (4), (b) (6) | 02 Oct 2020 20:46:49 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:14:58

[Indication](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:35 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'help prevent constipation from pain medication' | (b) (4) (b) (4), (b) (6) | 02 Oct 2020 20:46:49 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:14:58

[Dose per administration](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:35 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM). | (b) (4) (b) (4), (b) (6) | 10 Dec 2020 18:05:11 |
| Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' answered with 'updated' (Site from DM). | Alexandra Caillouet (b) (4) | 09 Dec 2020 20:51:00 |
| User entered '5' reason for change: Data Entry Error | Alexandra Caillouet (b) (4) | 09 Dec 2020 20:50:51 |
| User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM). | (b) (4), (b) (6) | 30 Nov 2020 19:40:47 |
| User entered '1' | (b) (4), (b) (6) | 02 Oct 2020 20:46:49 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:14:58

[Dose unit](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:35 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4) | 02 Oct 2020 20:49:02 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 02 Oct 2020 20:49:02 |
| User entered 'mg (mg)' reason for change: Data Entry Error | (b) (4), (b) (6) | 02 Oct 2020 20:49:02 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 02 Oct 2020 20:46:49 |
| User entered empty. | (b) (4), (b) (6) | 02 Oct 2020 20:46:49 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:14:58

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:35 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 02 Oct 2020 20:46:49 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:14:58

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:35 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'as needed (PRN)' | (b) (4) (b) (4), (b) (6) | 02 Oct 2020 20:46:49 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:14:58

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:35 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 02 Oct 2020 20:46:49 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:14:58

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:35 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'Oral (ORAL)' | (b) (4) (b) (4), (b) (6) | 02 Oct 2020 20:46:49 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:14:58

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:35 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 02 Oct 2020 20:46:49 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:14:58

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:35 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered '22 Sep 2020' | (b) (4) (b) (4), (b) (6) | 02 Oct 2020 20:46:49 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:14:58

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:35 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 02 Oct 2020 20:46:49 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:14:58

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:35 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'No (N)' reason for change: Data Entry Error | Crystal Rowell (b) (4) | 12 Nov 2020 20:40:51 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 02 Oct 2020 20:46:49 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:14:58

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:35 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered '29 Oct 2020' reason for change: Data Entry Error | (b) (4) | 12 Nov 2020 20:40:51 |
| User entered empty. | Crystal Rowell (b) (4) | 02 Oct 2020 20:46:49 |
| | (b) (4), (b) (6) | |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:14:58

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:35 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 02 Oct 2020 20:46:49 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:14:58

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:35 |
| User entered empty. | System | 02 Oct 2020 20:46:49 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:14:58

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:35 |
| User entered empty. | System | 02 Oct 2020 20:46:49 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:14:58

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:35 |
| User entered empty. | System | 02 Oct 2020 20:46:49 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:14:58

Name of Medication

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:41 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 31 Oct 2020 11:24:12 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 31 Oct 2020 11:24:12 |
| Data point term sent to Coder | System | 30 Oct 2020 19:21:07 |
| User entered 'apixaban' | Crystal Rowell (b) (4) | 30 Oct 2020 19:20:52 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:14:58

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:41 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'No (N)' | (b) (4) Crystal Rowell (b) (4) | 30 Oct 2020 19:20:52 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:14:58

[Indication](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:41 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'right axillary and brachial deep vein thrombosis' | Crystal Rowell (b) (4) | 30 Oct 2020 19:20:52 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:14:58

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:41 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered '5' | Crystal Rowell (b) (4) | 30 Oct 2020 19:20:52 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:14:58

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:41 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'mg (mg)' | (b) (4) Crystal Rowell (b) (4) | 30 Oct 2020 19:20:52 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:14:58

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:41 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered empty. | (b) (4) Crystal Rowell (b) (4) | 30 Oct 2020 19:20:52 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:14:58

[Frequency](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:41 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'twice daily (BID)' | (b) (4) Crystal Rowell (b) (4) | 30 Oct 2020 19:20:52 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:14:58

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:41 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered empty. | (b) (4) Crystal Rowell (b) (4) | 30 Oct 2020 19:20:52 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:14:58

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:41 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'Oral (ORAL)' | Crystal Rowell (b) (4) | 30 Oct 2020 19:20:52 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:14:58

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:41 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered empty. | Crystal Rowell (b) (4) | 30 Oct 2020 19:20:52 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:41 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered '20 Oct 2020' | Crystal Rowell (b) (4) | 30 Oct 2020 19:20:52 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:14:58

Start date completely unknown

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:41 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User closed query 'Start date is provided, however Start date completely unknown is checked. Please correct.' (Site from System). | (b) (4) | |
| User entered '0' reason for change: Data Entry Error | System | 30 Oct 2020 19:21:19 |
| User opened query 'Start date is provided, however Start date completely unknown is checked. Please correct.' (Site from System). | Crystal Rowell (b) (4) | 30 Oct 2020 19:21:19 |
| User entered '1' | (b) (4) | |
| | System | 30 Oct 2020 19:20:52 |
| | Crystal Rowell (b) (4) | 30 Oct 2020 19:20:52 |
| | (b) (4) | |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:14:58

[Ongoing?](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:41 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM). | (b) (4) | |
| Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'updated end date' (Site from DM). | (b) (4), (b) (6) | 13 Jan 2021 18:32:01 |
| Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'updated end date' (Site from DM). | Amy Thomassie (b) (4) | 12 Jan 2021 21:58:47 |
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4) | 12 Jan 2021 21:58:34 |
| User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM). | (b) (4), (b) (6) | 11 Jan 2021 05:55:42 |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 30 Oct 2020 19:21:19 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 30 Oct 2020 19:21:19 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Crystal Rowell (b) (4) | 30 Oct 2020 19:21:19 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 30 Oct 2020 19:20:52 |
| User entered empty. | Crystal Rowell (b) (4) | 30 Oct 2020 19:20:52 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:14:58

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:41 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered '20 Nov 2020' reason for change: Data Entry Error | (b) (4) | 12 Jan 2021 21:58:34 |
| User entered empty. | Amy Thomassie (b) (4) | 30 Oct 2020 19:20:52 |
| | (b) (4) | |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:14:58

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:41 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'No (N)' | Crystal Rowell (b) (4) | 30 Oct 2020 19:20:52 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:14:58

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:41 |
| User entered '2' | System | 30 Oct 2020 19:20:52 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:14:58

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:41 |
| User entered '1' | System | 30 Oct 2020 19:20:52 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:14:58

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:41 |
| User entered '804 (804)' | System | 30 Oct 2020 19:20:52 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:14:58

Name of Medication

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:46 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: DICLOFENAC - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 11 Nov 2020 23:36:37 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | (b) (4) | 11 Nov 2020 23:36:37 |
| Data point term sent to Coder | System | 11 Nov 2020 17:30:01 |
| Coding entries removed. | Crystal Rowell (b) (4) | 11 Nov 2020 17:29:28 |
| User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: DICLOFENAC - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 31 Oct 2020 11:18:19 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 31 Oct 2020 11:18:19 |
| Data point term sent to Coder | System | 30 Oct 2020 19:24:10 |
| User entered 'diclofenac EC' | Crystal Rowell (b) (4) | 30 Oct 2020 19:23:58 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:14:58

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:46 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'No (N)' | Crystal Rowell (b) (4) | 30 Oct 2020 19:23:58 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:14:58

[Indication](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:46 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'left hip pain due to worsening of anterior left pelvic ring non-union' reason for change: Data Entry Error | (b) (4) Crystal Rowell (b) (4) | 11 Nov 2020 17:29:28 |
| User entered 'left hip pain' | Crystal Rowell (b) (4) | 30 Oct 2020 19:23:58 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:14:58

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:46 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered '50' | Crystal Rowell (b) (4) | 30 Oct 2020 19:23:58 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:14:58

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:46 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'mg (mg)' | (b) (4) Crystal Rowell (b) (4) | 30 Oct 2020 19:23:58 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:14:58

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:46 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered empty. | (b) (4) Crystal Rowell (b) (4) | 30 Oct 2020 19:23:58 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:14:58

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:46 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'as needed (PRN)' | Crystal Rowell (b) (4) | 30 Oct 2020 19:23:58 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:14:58

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:46 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered empty. | (b) (4) Crystal Rowell (b) (4) | 30 Oct 2020 19:23:58 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:14:58

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:46 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'Oral (ORAL)' | Crystal Rowell (b) (4) | 30 Oct 2020 19:23:58 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:14:58

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:46 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered empty. | (b) (4) Crystal Rowell (b) (4) | 30 Oct 2020 19:23:58 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:14:58

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:46 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered '20 Oct 2020' | Crystal Rowell (b) (4) | 30 Oct 2020 19:23:58 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:14:58

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:46 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered '0' | Crystal Rowell (b) (4) | 30 Oct 2020 19:23:58 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:14:58

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:46 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'No (N)' reason for change: Data Entry Error | Crystal Rowell (b) (4) | 12 Nov 2020 20:11:58 |
| User entered 'Yes (Y)' | Crystal Rowell (b) (4) | 30 Oct 2020 19:23:58 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:14:58

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:46 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered '3 Nov 2020' reason for change: Data Entry Error | (b) (4) | 12 Nov 2020 20:11:58 |
| User entered empty. | Crystal Rowell (b) (4) | 30 Oct 2020 19:23:58 |
| | (b) (4) | |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:14:58

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:46 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'No (N)' | Crystal Rowell (b) (4) | 30 Oct 2020 19:23:58 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:14:58

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:46 |
| User entered empty. | System | 30 Oct 2020 19:23:58 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:14:58

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:46 |
| User entered empty. | System | 30 Oct 2020 19:23:58 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:14:58

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:46 |
| User entered empty. | System | 30 Oct 2020 19:23:58 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:14:58

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:52 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIMYCOBACTERIALS, ATC: DRUGS FOR TREATMENT OF LEPRO, ATC: DRUGS FOR TREATMENT OF LEPRO, PRODUCT: RIFAMPICIN, PRODUCTS YNOMY: RIFAMPIN - version WHODrug-Global-B3\202003. | Coder Import (b) (4) | 31 Oct 2020 00:59:08 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003. | Coder Import (b) (4) | 31 Oct 2020 00:59:08 |
| Data point term sent to Coder | System | 30 Oct 2020 19:26:11 |
| User entered 'Rifampin' | Crystal Rowell (b) (4) | 30 Oct 2020 19:25:34 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:14:58

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:52 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'No (N)' | Crystal Rowell (b) (4) | 30 Oct 2020 19:25:34 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:14:58

[Indication](#)

| Audit | User | Time (GMT) |
|---|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:52 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'post operative intra-abdominal abscess' | (b) (4) Crystal Rowell (b) (4) | 30 Oct 2020 19:25:34 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:14:58

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:52 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered '300' | Crystal Rowell (b) (4) | 30 Oct 2020 19:25:34 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:14:58

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:52 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'mg (mg)' | Crystal Rowell (b) (4) | 30 Oct 2020 19:25:34 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:14:58

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:52 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered empty. | (b) (4) Crystal Rowell (b) (4) | 30 Oct 2020 19:25:34 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:14:58

[Frequency](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:52 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'twice daily (BID)' | Crystal Rowell (b) (4) | 30 Oct 2020 19:25:34 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:14:58

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:52 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered empty. | (b) (4) Crystal Rowell (b) (4) | 30 Oct 2020 19:25:34 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:14:58

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:52 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'Oral (ORAL)' | Crystal Rowell (b) (4) | 30 Oct 2020 19:25:34 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:14:58

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:52 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered empty. | (b) (4) Crystal Rowell (b) (4) | 30 Oct 2020 19:25:34 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:14:58

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:52 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered '20 Oct 2020' | (b) (4) Crystal Rowell (b) (4) | 30 Oct 2020 19:25:34 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:14:58

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:52 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered '0' | Crystal Rowell (b) (4) | 30 Oct 2020 19:25:34 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:14:58

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:52 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4) | |
| | Crystal Rowell (b) (4) | 12 Nov 2020 20:00:45 |
| User entered 'Yes (Y)' | (b) (4) | |
| | Crystal Rowell (b) (4) | 30 Oct 2020 19:25:34 |
| | (b) (4) | |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:14:58

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:52 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered '3 Nov 2020' reason for change: Data Entry Error | (b) (4) | |
| | Crystal Rowell (b) (4) | 12 Nov 2020 20:00:45 |
| User entered empty. | (b) (4) | |
| | Crystal Rowell (b) (4) | 30 Oct 2020 19:25:34 |
| | (b) (4) | |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:14:58

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:52 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'No (N)' | Crystal Rowell (b) (4) | 30 Oct 2020 19:25:34 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:14:58

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:52 |
| User entered '2' | System | 30 Oct 2020 19:25:34 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:14:58

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:52 |
| User entered '1' | System | 30 Oct 2020 19:25:34 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:14:58

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:00:52 |
| User entered '804 (804)' | System | 30 Oct 2020 19:25:34 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:14:58

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:03 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FIRST-GENERATION CEPHALOSPORINS, PRODUCT: CEFRADINE, PRODUCTSYNONYM: ANCEF [CEFADINE] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 05 Nov 2020 20:59:39 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 05 Nov 2020 20:59:39 |
| Data point term sent to Coder | System | 30 Oct 2020 19:28:16 |
| Data point term sent to Coder | System | 30 Oct 2020 19:27:15 |
| User entered 'Ancef' | Crystal Rowell (b) (4) | 30 Oct 2020 19:26:58 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:14:58

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:03 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User closed query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the AE eCRF. Please review if the prophylaxis indication should be updated as appropriate and this field be updated to No. Otherwise, provide clarification.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 18 Jan 2021 16:04:53 |
| Query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the AE eCRF. Please review if the prophylaxis indication should be updated as appropriate and this field be updated to No. Otherwise, provide clarification.' answered with 'updated' (Site from DM). | Amy Thomassie (b) (4) (b) (4) | 16 Jan 2021 15:47:09 |
| User entered 'No (N)' reason for change: Data Entry Error | Amy Thomassie (b) (4) (b) (4) | 16 Jan 2021 15:47:02 |
| User opened query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the AE eCRF. Please review if the prophylaxis indication should be updated as appropriate and this field be updated to No. Otherwise, provide clarification.' (Site from DM). | (b) (4), (b) (6) | 15 Jan 2021 21:25:38 |
| User entered 'Yes (Y)' | Crystal Rowell (b) (4) (b) (4) | 30 Oct 2020 19:26:58 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:14:58

[Indication](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:03 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4) | |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 30 Oct 2020 19:27:52 |
| User entered 'post operative intra-abdominal abscess' reason for change: Data Entry Error | System | 30 Oct 2020 19:27:52 |
| User opened query 'Data is required. Please complete.' (Site from System). | Crystal Rowell (b) (4) | 30 Oct 2020 19:27:52 |
| User entered empty. | (b) (4) | |
| | System | 30 Oct 2020 19:26:58 |
| | Crystal Rowell (b) (4) | 30 Oct 2020 19:26:58 |
| | (b) (4) | |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:14:58

[Dose per administration](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:03 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4) | |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 30 Oct 2020 19:27:52 |
| User entered '2' reason for change: Data Entry Error | Crystal Rowell (b) (4) | 30 Oct 2020 19:27:52 |
| User opened query 'Data is required. Please complete.' (Site from System). | (b) (4) | |
| User entered empty. | System | 30 Oct 2020 19:26:58 |
| | Crystal Rowell (b) (4) | 30 Oct 2020 19:26:58 |
| | (b) (4) | |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:14:58

[Dose unit](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:03 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4) | |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 30 Oct 2020 19:27:52 |
| User entered 'g (g)' reason for change: Data Entry Error | Crystal Rowell (b) (4) | 30 Oct 2020 19:27:52 |
| User opened query 'Data is required. Please complete.' (Site from System). | (b) (4) | |
| User entered empty. | System | 30 Oct 2020 19:26:58 |
| | Crystal Rowell (b) (4) | 30 Oct 2020 19:26:58 |
| | (b) (4) | |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:14:58

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:03 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered empty. | (b) (4) Crystal Rowell (b) (4) | 30 Oct 2020 19:26:58 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:14:58

[Frequency](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:03 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4) | |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 30 Oct 2020 19:27:52 |
| User entered 'three times daily (TID)' reason for change: Data Entry Error | System | 30 Oct 2020 19:27:52 |
| User opened query 'Data is required. Please complete.' (Site from System). | Crystal Rowell (b) (4) | 30 Oct 2020 19:27:52 |
| User entered empty. | (b) (4) | |
| | System | 30 Oct 2020 19:26:58 |
| | Crystal Rowell (b) (4) | 30 Oct 2020 19:26:58 |
| | (b) (4) | |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:14:58

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:03 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered empty. | (b) (4) Crystal Rowell (b) (4) | 30 Oct 2020 19:26:58 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:14:58

[Route of administration](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:03 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4) | |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 30 Oct 2020 19:27:52 |
| User entered 'Intravenous (INTRAVENOUS)' reason for change: Data Entry Error | System | 30 Oct 2020 19:27:52 |
| User opened query 'Data is required. Please complete.' (Site from System). | Crystal Rowell (b) (4) | 30 Oct 2020 19:27:52 |
| User entered empty. | (b) (4) | |
| | System | 30 Oct 2020 19:26:58 |
| | Crystal Rowell (b) (4) | 30 Oct 2020 19:26:58 |
| | (b) (4) | |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:14:58

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:03 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered empty. | (b) (4) Crystal Rowell (b) (4) | 30 Oct 2020 19:26:58 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:14:58

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:03 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User closed query 'Per DM CLR: Con Med start date is after the end date of the corresponding AE. Please review and reconcile Con Med and AE start/end dates as appropriate. Otherwise, provide explanation' (Site from DM). | (b) (4) (b) (4), (b) (6) | 05 Apr 2021 15:01:53 |
| Query 'Per DM CLR: Con Med start date is after the end date of the corresponding AE. Please review and reconcile Con Med and AE start/end dates as appropriate. Otherwise, provide explanation' answered with 'Antibiotic given to prevent further infection following drainage/treatment of abscess.' (Site from DM). | Alexandra Caillouet (b) (4) | 01 Apr 2021 17:27:24 |
| User opened query 'Per DM CLR: Con Med start date is after the end date of the corresponding AE. Please review and reconcile Con Med and AE start/end dates as appropriate. Otherwise, provide explanation' (Site from DM). | (b) (4), (b) (6) | 31 Mar 2021 09:23:44 |
| User closed query 'Start date is missing and Start date System completely unknown is not checked. Please provide.' (Site from System). | | 30 Oct 2020 19:27:52 |
| User entered '20 Oct 2020' reason for change: Data Entry Error | Crystal Rowell (b) (4) | 30 Oct 2020 19:27:52 |
| User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System). | System | 30 Oct 2020 19:26:58 |
| User entered empty. | Crystal Rowell (b) (4) (b) (4) | 30 Oct 2020 19:26:58 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:14:58

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:03 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered '0' | (b) (4) Crystal Rowell (b) (4) | 30 Oct 2020 19:26:58 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:14:58

[Ongoing?](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:03 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'No (N)' reason for change: Data Entry Error | Crystal Rowell (b) (4) | 12 Nov 2020 20:00:04 |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 30 Oct 2020 19:27:52 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 30 Oct 2020 19:27:52 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Crystal Rowell (b) (4) | 30 Oct 2020 19:27:52 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 30 Oct 2020 19:26:58 |
| User entered empty. | Crystal Rowell (b) (4) | 30 Oct 2020 19:26:58 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:14:58

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:03 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered '3 Nov 2020' reason for change: Data Entry Error | Crystal Rowell (b) (4) | 12 Nov 2020 20:00:04 |
| User entered empty. | Crystal Rowell (b) (4) | 30 Oct 2020 19:26:58 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:14:58

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:03 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4) | |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 30 Oct 2020 19:27:52 |
| User entered 'No (N)' reason for change: Data Entry Error | Crystal Rowell (b) (4) | 30 Oct 2020 19:27:52 |
| User opened query 'Data is required. Please complete.' (Site from System). | (b) (4) | |
| User entered empty. | System | 30 Oct 2020 19:26:58 |
| | Crystal Rowell (b) (4) | 30 Oct 2020 19:26:58 |
| | (b) (4) | |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:14:58

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:03 |
| User entered '3' | System | 30 Oct 2020 19:27:52 |
| User entered empty. | System | 30 Oct 2020 19:26:58 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:14:58

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:03 |
| User entered '1' | System | 30 Oct 2020 19:27:52 |
| User entered empty. | System | 30 Oct 2020 19:26:58 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:14:58

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:03 |
| User entered '804 (804)' | System | 30 Oct 2020 19:27:52 |
| User entered empty. | System | 30 Oct 2020 19:26:58 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:14:58

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: IRON PREPARATIONS, ATC: IRON BIVALENT, ORAL PREPARATIONS, PRODUCT: FERROUS SULFATE - version WHODrug-Global-B3\\202003. | (b) (4) Coder Import (b) (4) | 31 Oct 2020 11:15:17 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 31 Oct 2020 11:15:17 |
| Data point term sent to Coder | System | 30 Oct 2020 19:30:18 |
| User entered 'ferrous sulfate' | Crystal Rowell (b) (4) (b) (4) | 30 Oct 2020 19:29:44 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:14:58

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User closed query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 18 Jan 2021 16:05:15 |
| Query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification.' answered with 'updated' (Site from DM). | Amy Thomassie (b) (4) (b) (4) | 16 Jan 2021 15:51:06 |
| User entered 'No (N)' reason for change: Data Entry Error | Amy Thomassie (b) (4) (b) (4) | 16 Jan 2021 15:51:00 |
| User opened query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification.' (Site from DM). | (b) (4), (b) (6) | 15 Jan 2021 21:27:39 |
| User entered 'Yes (Y)' | Crystal Rowell (b) (4) (b) (4) | 30 Oct 2020 19:29:44 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:14:58

[Indication](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| | (b) (4) | |
| User entered 'alpha thalassemia' | Crystal Rowell (b) (4) | 30 Oct 2020 19:29:44 |
| | (b) (4) | |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:14:58

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---|-----------------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 18 Jan 2021 16:05:22 |
| Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'confirmed as correct per EMR' (Site from DM). | Amy Thomassie (b) (4) (b) (4) | 16 Jan 2021 15:51:26 |
| User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM). | (b) (4), (b) (6) | 15 Jan 2021 21:27:16 |
| User entered '324' | Crystal Rowell (b) (4) (b) (4) | 30 Oct 2020 19:29:44 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:14:58

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| | (b) (4) | |
| User entered 'mg (mg)' | Crystal Rowell (b) (4) | 30 Oct 2020 19:29:44 |
| | (b) (4) | |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:14:58

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| | (b) (4) | |
| User entered empty. | Crystal Rowell (b) (4) | 30 Oct 2020 19:29:44 |
| | (b) (4) | |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:14:58

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|--|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'once daily (QD)' | (b) (4) Crystal Rowell (b) (4) (b) (4) | 30 Oct 2020 19:29:44 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:14:58

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| | (b) (4) | |
| User entered empty. | Crystal Rowell (b) (4) | 30 Oct 2020 19:29:44 |
| | (b) (4) | |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:14:58

[Route of administration](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| | (b) (4) | |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 30 Oct 2020 19:29:50 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 30 Oct 2020 19:29:50 |
| User entered 'Oral (ORAL)' reason for change: Data Entry Error | Crystal Rowell (b) (4) | 30 Oct 2020 19:29:50 |
| | (b) (4) | |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 30 Oct 2020 19:29:44 |
| User entered empty. | Crystal Rowell (b) (4) | 30 Oct 2020 19:29:44 |
| | (b) (4) | |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:14:58

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| | (b) (4) | |
| User entered empty. | Crystal Rowell (b) (4) | 30 Oct 2020 19:29:44 |
| | (b) (4) | |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:14:58

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| | (b) (4) | |
| User entered '20 Oct 2020' | Crystal Rowell (b) (4) | 30 Oct 2020 19:29:44 |
| | (b) (4) | |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:14:58

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| | (b) (4) | |
| User entered '0' | Crystal Rowell (b) (4) | 30 Oct 2020 19:29:44 |
| | (b) (4) | |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:14:58

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Crystal Rowell (b) (4) | 30 Oct 2020 19:29:44 |
| | (b) (4) | |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:14:58

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| | (b) (4) | |
| User entered empty. | Crystal Rowell (b) (4) | 30 Oct 2020 19:29:44 |
| | (b) (4) | |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:14:58

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| | (b) (4) | |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 30 Oct 2020 19:29:54 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 30 Oct 2020 19:29:54 |
| User entered 'No (N)' reason for change: Data Entry Error | Crystal Rowell (b) (4) | 30 Oct 2020 19:29:54 |
| | (b) (4) | |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 30 Oct 2020 19:29:44 |
| User entered empty. | Crystal Rowell (b) (4) | 30 Oct 2020 19:29:44 |
| | (b) (4) | |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:14:58

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 30 Oct 2020 19:29:44 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:14:58

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 30 Oct 2020 19:29:44 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:14:58

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 30 Oct 2020 19:29:44 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:14:58

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:25 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: CALCIUM CHLORIDE;POTASSIUM CHLORIDE;SODIUM LACTATE, PRODUCTSYNONYM: LACTATED RINGERS - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 12 Nov 2020 20:06:35 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | (b) (4) | 12 Nov 2020 20:06:35 |
| Data point term sent to Coder | System | 12 Nov 2020 20:05:44 |
| User entered 'Lactated Ringers' | Crystal Rowell (b) (4) | 12 Nov 2020 20:04:53 |
| | (b) (4) | |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:14:58

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:25 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'No (N)' | Crystal Rowell (b) (4) | 12 Nov 2020 20:04:53 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:14:58

[Indication](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:25 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'IV hydration secondary to post operative intra-abdominal abscess' | Crystal Rowell (b) (4) | 12 Nov 2020 20:04:53 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:14:58

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:25 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered '1000' | Crystal Rowell (b) (4) | 12 Nov 2020 20:04:53 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:14:58

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:25 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'mL (mL)' | Crystal Rowell (b) (4) | 12 Nov 2020 20:04:53 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:14:58

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:25 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered empty. | Crystal Rowell (b) (4) | 12 Nov 2020 20:04:53 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:14:58

[Frequency](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:25 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'once (ONCE)' | Crystal Rowell (b) (4) | 12 Nov 2020 20:04:53 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:14:58

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:25 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered empty. | (b) (4) Crystal Rowell (b) (4) | 12 Nov 2020 20:04:53 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:14:58

[Route of administration](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:25 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'Intravenous (INTRAVENOUS)' | Crystal Rowell (b) (4) | 12 Nov 2020 20:04:53 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:14:58

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:25 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered empty. | Crystal Rowell (b) (4) | 12 Nov 2020 20:04:53 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:14:58

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:25 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered '12 Oct 2020' | Crystal Rowell (b) (4) | 12 Nov 2020 20:04:53 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:14:58

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:25 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered '0' | Crystal Rowell (b) (4) | 12 Nov 2020 20:04:53 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:14:58

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:25 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'No (N)' | Crystal Rowell (b) (4) | 12 Nov 2020 20:04:53 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:14:58

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:25 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered '12 Oct 2020' | Crystal Rowell (b) (4) | 12 Nov 2020 20:04:53 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:14:58

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:25 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'No (N)' | Crystal Rowell (b) (4) | 12 Nov 2020 20:04:53 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:14:58

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:25 |
| User entered empty. | System | 12 Nov 2020 20:04:53 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:14:58

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:25 |
| User entered empty. | System | 12 Nov 2020 20:04:53 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:14:58

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:25 |
| User entered empty. | System | 12 Nov 2020 20:04:53 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:14:58

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:31 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: OTHER ANTIBACTERIALS, PRODUCT: LINEZOLID - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 13 Nov 2020 04:36:44 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 13 Nov 2020 04:36:44 |
| Data point term sent to Coder | System | 12 Nov 2020 20:15:04 |
| User entered 'linezolid' | Crystal Rowell (b) (4) | 12 Nov 2020 20:14:26 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:14:58

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:31 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'No (N)' | Crystal Rowell (b) (4) | 12 Nov 2020 20:14:26 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:14:58

[Indication](#)

| Audit | User | Time (GMT) |
|---|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:31 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'post-operative intrabdominal abscess' | (b) (4) Crystal Rowell (b) (4) | 12 Nov 2020 20:14:26 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:14:58

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:31 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered '600' | Crystal Rowell (b) (4) | 12 Nov 2020 20:14:26 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:14:58

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:31 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'mg (mg)' | Crystal Rowell (b) (4) | 12 Nov 2020 20:14:26 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:14:58

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:31 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered empty. | (b) (4) Crystal Rowell (b) (4) | 12 Nov 2020 20:14:26 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:14:58

[Frequency](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:31 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'twice daily (BID)' | Crystal Rowell (b) (4) | 12 Nov 2020 20:14:26 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:14:58

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:31 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered empty. | (b) (4) Crystal Rowell (b) (4) | 12 Nov 2020 20:14:26 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:14:58

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:31 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'Oral (ORAL)' | Crystal Rowell (b) (4) | 12 Nov 2020 20:14:26 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:14:58

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:31 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered empty. | Crystal Rowell (b) (4) | 12 Nov 2020 20:14:26 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:14:58

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:31 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered '4 Nov 2020' | Crystal Rowell (b) (4) | 12 Nov 2020 20:14:26 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:14:58

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:31 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered '0' | Crystal Rowell (b) (4) | 12 Nov 2020 20:14:26 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:14:58

[Ongoing?](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:31 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'No (N)' reason for change: New Information | (b) (4), (b) (6) | 19 Nov 2020 22:28:45 |
| User entered 'Yes (Y)' | Crystal Rowell (b) (4) | 12 Nov 2020 20:14:26 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:14:58

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:31 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered '13 Nov 2020' reason for change: New Information | (b) (4), (b) (6) | 19 Nov 2020 22:28:45 |
| User entered empty. | Crystal Rowell (b) (4) | 12 Nov 2020 20:14:26 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:14:58

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:31 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'No (N)' | Crystal Rowell (b) (4) | 12 Nov 2020 20:14:26 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:14:58

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:31 |
| User entered '2' | System | 12 Nov 2020 20:14:26 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:14:58

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:31 |
| User entered '1' | System | 12 Nov 2020 20:14:26 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:14:58

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:31 |
| User entered '804 (804)' | System | 12 Nov 2020 20:14:26 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:14:58

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:36 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: OTHER ANTIBACTERIALS, PRODUCT: DAPTOMYCIN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 12 Nov 2020 21:27:37 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 12 Nov 2020 21:27:37 |
| Data point term sent to Coder | System | 12 Nov 2020 20:39:48 |
| User entered 'Daptomycin' | Crystal Rowell (b) (4) | 12 Nov 2020 20:38:49 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:14:58

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:36 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'No (N)' | Crystal Rowell (b) (4) | 12 Nov 2020 20:38:49 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:14:58

[Indication](#)

| Audit | User | Time (GMT) |
|---|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:36 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'Post operative intrabdominal abscess' | (b) (4) Crystal Rowell (b) (4) | 12 Nov 2020 20:38:49 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:14:58

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:36 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered '420' | Crystal Rowell (b) (4) | 12 Nov 2020 20:38:49 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:14:58

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:36 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'mg (mg)' | (b) (4) Crystal Rowell (b) (4) | 12 Nov 2020 20:38:49 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:14:58

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:36 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered empty. | (b) (4) Crystal Rowell (b) (4) | 12 Nov 2020 20:38:49 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:14:58

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:36 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'once daily (QD)' | Crystal Rowell (b) (4) | 12 Nov 2020 20:38:49 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:14:58

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:36 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered empty. | (b) (4) Crystal Rowell (b) (4) | 12 Nov 2020 20:38:49 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:14:58

[Route of administration](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:36 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'Intravenous (INTRAVENOUS)' | Crystal Rowell (b) (4) | 12 Nov 2020 20:38:49 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:14:58

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:36 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered empty. | Crystal Rowell (b) (4) | 12 Nov 2020 20:38:49 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:14:58

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:36 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User closed query 'Per DM CLR: Con Med start date is after the end date of the corresponding AE. Please review and reconcile Con Med and AE start/end dates as appropriate. Otherwise, provide explanation' (Site from DM). | (b) (4) (b) (4), (b) (6) | 05 Apr 2021 15:03:20 |
| Query 'Per DM CLR: Con Med start date is after the end date of the corresponding AE. Please review and reconcile Con Med and AE start/end dates as appropriate. Otherwise, provide explanation' answered with 'Antibiotic was used to help treat and prevent further infection following post operative intraabdominal abscess' (Site from DM). | Alexandra Caillouet (b) (4) | 01 Apr 2021 17:29:58 |
| User opened query 'Per DM CLR: Con Med start date is after the end date of the corresponding AE. Please review and reconcile Con Med and AE start/end dates as appropriate. Otherwise, provide explanation' (Site from DM). | (b) (4), (b) (6) | 31 Mar 2021 09:26:33 |
| User entered '9 Nov 2020' | Crystal Rowell (b) (4) (b) (4) | 12 Nov 2020 20:38:49 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:14:58

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:36 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered '0' | Crystal Rowell (b) (4) | 12 Nov 2020 20:38:49 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:14:58

[Ongoing?](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:36 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM). | (b) (4) | |
| Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'updated stop date ' (Site from DM). | (b) (4), (b) (6) | 13 Jan 2021 18:31:41 |
| Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'updated stop date ' (Site from DM). | Amy Thomassie (b) (4) | 12 Jan 2021 22:12:02 |
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4) | |
| User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM). | (b) (4), (b) (6) | 11 Jan 2021 05:55:27 |
| User entered 'Yes (Y)' | Crystal Rowell (b) (4) | 12 Nov 2020 20:38:49 |
| | (b) (4) | |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:14:58

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:36 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered '19 Nov 2020' reason for change: Data Entry Error | (b) (4) | 12 Jan 2021 22:11:08 |
| User entered empty. | Amy Thomassie (b) (4) | 12 Jan 2021 22:11:08 |
| | (b) (4) | |
| | Crystal Rowell (b) (4) | 12 Nov 2020 20:38:49 |
| | (b) (4) | |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:14:58

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:36 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4) | |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 12 Nov 2020 20:38:59 |
| User entered 'No (N)' reason for change: Data Entry Error | Crystal Rowell (b) (4) | 12 Nov 2020 20:38:59 |
| User opened query 'Data is required. Please complete.' (Site from System). | (b) (4) | |
| User entered empty. | System | 12 Nov 2020 20:38:49 |
| | Crystal Rowell (b) (4) | 12 Nov 2020 20:38:49 |
| | (b) (4) | |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:14:58

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:36 |
| User entered '1' | System | 12 Nov 2020 20:38:49 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:14:58

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:36 |
| User entered '1' | System | 12 Nov 2020 20:38:49 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:14:58

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:36 |
| User entered '804 (804)' | System | 12 Nov 2020 20:38:49 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:14:58

Name of Medication

| Audit | User | Time (GMT) |
|---|----------------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening OSTEOPOROSIS should be recorded, and update con med indication or provide clarification. ' (Site from DM). | (b) (4) (b) (4), (b) (6) | 18 Jan 2021 16:05:45 |
| Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening OSTEOPOROSIS should be recorded, and update con med indication or provide clarification. ' answered with 'not worsening' (Site from DM). | Amy Thomassie (b) (4) (b) (4) | 16 Jan 2021 15:52:24 |
| User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening OSTEOPOROSIS should be recorded, and update con med indication or provide clarification. ' (Site from DM). | (b) (4), (b) (6) | 15 Jan 2021 21:30:02 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, PRODUCT: CALCIUM - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 19 Nov 2020 22:35:50 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 19 Nov 2020 22:35:50 |
| Data point term sent to Coder | System | 19 Nov 2020 22:34:42 |
| User entered 'CALCIUM' | (b) (4), (b) (6) | 19 Nov 2020 22:33:54 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:14:58

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 19 Nov 2020 22:33:54 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:14:58

[Indication](#)

| Audit | User | Time (GMT) |
|-----------------------------|-----------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'OSTEOPOROSIS' | (b) (4) (b) (4), (b) (6) | 19 Nov 2020 22:33:54 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:14:58

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered '500' | (b) (4) (b) (4), (b) (6) | 19 Nov 2020 22:33:54 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:14:58

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'mg (mg)' | (b) (4) (b) (4), (b) (6) | 19 Nov 2020 22:33:54 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:14:58

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 19 Nov 2020 22:33:54 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:14:58

[Frequency](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'twice daily (BID)' | (b) (4) (b) (4), (b) (6) | 19 Nov 2020 22:33:54 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:14:58

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 19 Nov 2020 22:33:54 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:14:58

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'Oral (ORAL)' | (b) (4) (b) (4), (b) (6) | 19 Nov 2020 22:33:54 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:14:58

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 19 Nov 2020 22:33:54 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered '13 Nov 2020' | (b) (4) (b) (4), (b) (6) | 19 Nov 2020 22:33:54 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:14:58

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 19 Nov 2020 22:33:54 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:14:58

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 19 Nov 2020 22:33:54 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:14:58

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 19 Nov 2020 22:33:54 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:14:58

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 19 Nov 2020 22:33:54 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:14:58

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '2' | System | 19 Nov 2020 22:33:54 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:14:58

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 19 Nov 2020 22:33:54 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:14:58

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 19 Nov 2020 22:33:54 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:14:58

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:43 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening OSTEOPOROSIS should be recorded, and update con med indication or provide clarification. ' (Site from DM). | (b) (4) (b) (4), (b) (6) | 01 Feb 2021 15:21:15 |
| Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening OSTEOPOROSIS should be recorded, and update con med indication or provide clarification. ' answered with 'not worsening of osteoporosis. ' (Site from DM). | Amy Thomassie (b) (4) (b) (4) | 29 Jan 2021 20:26:14 |
| User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening OSTEOPOROSIS should be recorded, and update con med indication or provide clarification. ' (Site from DM). | (b) (4), (b) (6) | 29 Jan 2021 19:41:53 |
| User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: DRUGS FOR TREATMENT OF BONE DISEASES, ATC: DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION, ATC: OTHER DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION, PRODUCT: DENOSUMAB, PRODUCTSYNONYM: PROLIA - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 19 Nov 2020 22:38:04 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 19 Nov 2020 22:38:04 |
| Data point term sent to Coder | System | 19 Nov 2020 22:36:43 |
| User entered 'PROLIA' | (b) (4), (b) (6) | 19 Nov 2020 22:36:16 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:14:58

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:43 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'No (N)' | (b) (4), (b) (6) | 19 Nov 2020 22:36:16 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:14:58

[Indication](#)

| Audit | User | Time (GMT) |
|-----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:43 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'OSTEOPOROSIS' | (b) (4), (b) (6) | 19 Nov 2020 22:36:16 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:14:58

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:43 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered '60' | (b) (4), (b) (6) | 19 Nov 2020 22:36:16 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:14:58

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:43 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'mg (mg)' | (b) (4) (b) (4), (b) (6) | 19 Nov 2020 22:36:16 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:14:58

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:43 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 19 Nov 2020 22:36:16 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:14:58

[Frequency](#)

| Audit | User | Time (GMT) |
|------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:43 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'other (OTHER)' | (b) (4) (b) (4), (b) (6) | 19 Nov 2020 22:36:16 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:14:58

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|-------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:43 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'EVERY 6 MONTHS' | (b) (4) (b) (4), (b) (6) | 19 Nov 2020 22:36:16 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:14:58

[Route of administration](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:43 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'Subcutaneous (SUBCUTANEOUS)' | (b) (4) (b) (4), (b) (6) | 19 Nov 2020 22:36:16 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:14:58

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:43 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 19 Nov 2020 22:36:16 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:14:58

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:43 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered '05 Nov 2020' | (b) (4) (b) (4), (b) (6) | 19 Nov 2020 22:36:16 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:14:58

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:43 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered '0' | (b) (4), (b) (6) | 19 Nov 2020 22:36:16 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:14:58

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:43 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'No (N)' | (b) (4), (b) (6) | 19 Nov 2020 22:36:16 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:14:58

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:43 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered '05 Nov 2020' | (b) (4), (b) (6) | 19 Nov 2020 22:36:16 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:14:58

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:43 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'No (N)' | (b) (4), (b) (6) | 19 Nov 2020 22:36:16 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:14:58

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:43 |
| User entered empty. | System | 19 Nov 2020 22:36:16 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:14:58

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:43 |
| User entered empty. | System | 19 Nov 2020 22:36:16 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:14:58

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 03:01:43 |
| User entered empty. | System | 19 Nov 2020 22:36:16 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:14:58

Name of Medication

| Audit | User | Time (GMT) |
|--|--|--|
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: TETRACYCLINES, ATC: TETRACYCLINES, PRODUCT: DOXYCYCLINE - version WHODrug-Global-B3\\202003. | (b) (4) Coder Import (b) (4) | 04 Feb 2021 12:35:07 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 04 Feb 2021 12:35:07 |
| Data point term sent to Coder Coding entries removed. | System Alexandra Caillouet | 03 Feb 2021 17:58:04 03 Feb 2021 17:58:04 |
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: TETRACYCLINES, ATC: TETRACYCLINES, PRODUCT: DOXYCYCLINE - version WHODrug-Global-B3\\202003. | (b) (4) Coder Import (b) (4) (b) (4) | 08 Jan 2021 14:58:40 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 08 Jan 2021 14:58:40 |
| Data point term sent to Coder Coding entries removed. | System (b) (4), (b) (6) | 07 Jan 2021 20:04:24 07 Jan 2021 20:03:39 |
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: TETRACYCLINES, ATC: TETRACYCLINES, PRODUCT: DOXYCYCLINE HYCLATE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 30 Nov 2020 23:29:03 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 30 Nov 2020 23:29:03 |
| Data point term sent to Coder | System | 30 Nov 2020 20:03:46 |
| Data point term sent to Coder | System | 30 Nov 2020 19:56:39 |
| User entered 'Doxycycline hyc' | (b) (4), (b) (6) | 30 Nov 2020 19:56:37 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:14:58

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | (b) (4) (b) (4), (b) (6) | 07 Jan 2021 20:03:39 |
| User entered 'No (N)' | (b) (4), (b) (6) | 30 Nov 2020 19:56:37 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:14:58

[Indication](#)

| Audit | User | Time (GMT) |
|---|--------------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM). | (b) (4) (b) (4), (b) (6) | 04 Feb 2021 17:24:15 |
| Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' answered with 'Antibiotics prescribed prophylactically to prevent joint infection. No AE or MH needed. ' (Site from DM). | Alexandra Caillouet (b) (4) | 03 Feb 2021 17:58:10 |
| User entered 'JOINT INFECTION Prophylaxis - Suppression Antibiotics' reason for change: Data Entry Error | Alexandra Caillouet (b) (4) | 03 Feb 2021 17:58:04 |
| User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM). | (b) (4), (b) (6) | 29 Jan 2021 19:43:15 |
| User entered 'joint Infection' reason for change: Data Entry Error | (b) (4), (b) (6) | 07 Jan 2021 20:03:39 |
| User entered 'Bacterial INFECTION' reason for change: Data Entry Error | | 30 Nov 2020 20:02:52 |
| User entered 'infection' | | 30 Nov 2020 19:56:37 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:14:58

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered '100' | (b) (4) (b) (4), (b) (6) | 30 Nov 2020 19:56:37 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:14:58

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'mg (mg)' | (b) (4) (b) (4), (b) (6) | 30 Nov 2020 19:56:37 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:14:58

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 30 Nov 2020 19:56:37 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:14:58

[Frequency](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'twice daily (BID)' | (b) (4) (b) (4), (b) (6) | 30 Nov 2020 19:56:37 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:14:58

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 30 Nov 2020 19:56:37 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:14:58

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'Oral (ORAL)' | (b) (4) (b) (4), (b) (6) | 30 Nov 2020 19:56:37 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:14:58

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 30 Nov 2020 19:56:37 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered '24 Nov 2020' | (b) (4) (b) (4), (b) (6) | 30 Nov 2020 19:56:37 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:14:58

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 30 Nov 2020 19:56:37 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:14:58

[Ongoing?](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User closed query 'Per DM CLR: Please verify if end date should be added as this duration is not expected for this medication. Update the eCRF as appropriate. Otherwise, provide explanation. ' (Site from DM). | (b) (4) (b) (4), (b) (6) | 05 Apr 2021 15:04:05 |
| Query 'Per DM CLR: Please verify if end date should be added as this duration is not expected for this medication. Update the eCRF as appropriate. Otherwise, provide explanation. ' answered with 'Prescribed medicine for 6 months for prophylaxis of joint/bone infection. Started 24NOV2020 and should complete around May 2021. ' (Site from DM). | Alexandra Caillouet (b) (4) | 01 Apr 2021 17:33:11 |
| User opened query 'Per DM CLR: Please verify if end date should be added as this duration is not expected for this medication. Update the eCRF as appropriate. Otherwise, provide explanation. ' (Site from DM). | (b) (4), (b) (6) | 31 Mar 2021 09:26:58 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 30 Nov 2020 19:56:37 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:14:58

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 30 Nov 2020 19:56:37 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:14:58

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 30 Nov 2020 19:56:37 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:14:58

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '2' | System | 30 Nov 2020 19:56:37 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:14:58

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 30 Nov 2020 19:56:37 |

US3362244

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:14:58

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 30 Nov 2020 19:56:37 |

US3362244

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:14:58

[Were any concomitant procedures performed?](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 06:00:37 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User closed query 'Per ETRTR: According to SAE "Worsening of Anterior Left Pelvic Ring Non-union" page, Procedure was performed. Please add Procedures details for SAE "Worsening of Anterior Left Pelvic Ring Non-union" within ConProcedures page, thanks.' (Site from CRA). | (b) (4) (b) (4), (b) (6) | 17 Jan 2021 19:44:10 |
| Query 'Per ETRTR: According to SAE "Worsening of Anterior Left Pelvic Ring Non-union" page, Procedure was performed. Please add Procedures details for SAE "Worsening of Anterior Left Pelvic Ring Non-union" within ConProcedures page, thanks.' answered with 'per query UPDATED ' (Site from CRA). | (b) (4), (b) (6) | 10 Nov 2020 22:01:05 |
| User opened query 'Per ETRTR: According to SAE "Worsening of Anterior Left Pelvic Ring Non-union" page, Procedure was performed. Please add Procedures details for SAE "Worsening of Anterior Left Pelvic Ring Non-union" within ConProcedures page, thanks.' (Site from CRA). | (b) (4), (b) (6) | 05 Nov 2020 15:34:52 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | (b) (4), (b) (6) | 16 Oct 2020 18:43:04 |
| User entered 'No (N)' | (b) (4), (b) (6) | 25 Aug 2020 19:12:24 |

US3362244

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:14:58

Procedure/Surgery date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered '13 Oct 2020' | (b) (4) (b) (4), (b) (6) | 16 Oct 2020 18:44:11 |

US3362244

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:14:58

[Procedure/Surgery](#)

| Audit | User | Time (GMT) |
|------------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'DRAINAGE OF ABSCESS' | (b) (4) (b) (4), (b) (6) | 16 Oct 2020 18:44:11 |

US3362244

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:14:58

[Indication](#)

| Audit | User | Time (GMT) |
|-----------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'Adverse Event (AE)' | (b) (4) (b) (4), (b) (6) | 16 Oct 2020 18:44:11 |

US3362244

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:14:58

[If indication is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 16 Oct 2020 18:44:11 |

US3362244

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:14:58

Procedure/Surgery date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 07:46:30 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered '29 Sep 2020' | (b) (4), (b) (6) | 10 Nov 2020 22:00:54 |

US3362244

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:14:58

[Procedure/Surgery](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 07:46:30 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'left pelvic ring fracture nonunion repair' | (b) (4), (b) (6) | 10 Nov 2020 22:00:54 |

US3362244

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:14:58

[Indication](#)

| Audit | User | Time (GMT) |
|-----------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 07:46:30 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'Adverse Event (AE)' | (b) (4), (b) (6) | 10 Nov 2020 22:00:54 |

US3362244

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:14:58

If indication is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 07:46:30 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered empty. | (b) (4), (b) (6) | 10 Nov 2020 22:00:54 |

US3362244

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:14:58

Procedure/Surgery date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 07:46:35 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered '20 Oct 2020' | Amy Thomassie (b) (4) | 23 Jan 2021 20:06:46 |

US3362244

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:14:58

[Procedure/Surgery](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 07:46:35 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'PICC LINE PLACEMENT left arm' | Amy Thomassie (b) (4) | 23 Jan 2021 20:07:42 |
| reason for change: Data Entry Error | (b) (4) | |
| User entered 'PICC line placement' | Amy Thomassie (b) (4) | 23 Jan 2021 20:06:46 |
| | (b) (4) | |

US3362244

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:14:58

[Indication](#)

| Audit | User | Time (GMT) |
|-----------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 07:46:35 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'Adverse Event (AE)' | Amy Thomassie (b) (4) | 23 Jan 2021 20:06:46 |

US3362244

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:14:58

If indication is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 07:46:35 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered empty. | Amy Thomassie (b) (4) | 23 Jan 2021 20:06:46 |

US3362244

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:14:58

Procedure/Surgery date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 07:46:37 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered '18 Oct 2020' | Amy Thomassie (b) (4) | 23 Jan 2021 20:07:31 |

US3362244

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:14:58

[Procedure/Surgery](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 07:46:37 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'PICC line placement right arm' | Amy Thomassie (b) (4) | 23 Jan 2021 20:07:31 |

US3362244

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:14:58

[Indication](#)

| Audit | User | Time (GMT) |
|-----------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 07:46:37 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered 'Adverse Event (AE)' | Amy Thomassie (b) (4) | 23 Jan 2021 20:07:31 |

US3362244

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:14:58

If indication is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 07:46:37 |
| User signature succeeded. | Jordan Whatley (b) (4) | 09 Apr 2021 00:58:08 |
| User entered empty. | Amy Thomassie (b) (4) | 23 Jan 2021 20:07:31 |

US3362244

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:14:58

Date of dosing discontinuation (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 12:59:55 |
| User closed query 'The page is only applicable to Part A of the study. The subject did not have 2 doses of IP, thus this page should be completed.' (Site from CRA). | (b) (4), (b) (6) | 26 Apr 2021 21:30:58 |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| User closed query 'Date of dosing discontinuation is prior to Randomization Date. Please verify and reconcile.' (Site from System). | (b) (4) | 25 Jan 2021 23:06:27 |
| User closed query 'Date of dosing discontinuation is prior to ICF Date. Please verify and reconcile.' (Site from System). | System | 25 Jan 2021 23:06:27 |
| User entered '23 Sep 2020' reason for change: Per Query Resolution | Alexandra Caillouet (b) (4) | 25 Jan 2021 23:06:27 |
| Query 'The page is only applicable to Part A of the study. The subject did not have 2 doses of IP, thus this page should be completed.' answered with 'updated' (Site from CRA). | Alexandra Caillouet (b) (4) | 25 Jan 2021 23:05:47 |
| User opened query 'Date of dosing discontinuation is prior to Randomization Date. Please verify and reconcile.' (Site from System). | System | 25 Jan 2021 23:05:40 |
| User opened query 'Date of dosing discontinuation is prior to ICF Date. Please verify and reconcile.' (Site from System). | System | 25 Jan 2021 23:05:40 |
| User entered '23 Sep 2019' reason for change: Per Query Resolution | Alexandra Caillouet (b) (4) | 25 Jan 2021 23:05:40 |
| User opened query 'The page is only applicable to Part A of the study. The subject did not have 2 doses of IP, thus this page should be completed.' (Site from CRA). | (b) (4), (b) (6) | 22 Jan 2021 00:58:54 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4), (b) (6) | 12 Jan 2021 17:46:01 |
| Query 'Data is required. Please complete.' answered with 'patient returned for unblinding and wanted dose' (Site from System). | Crystal Rowell (b) (4) | 11 Jan 2021 23:13:02 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 11 Jan 2021 23:12:38 |
| User entered empty; reason for change Per Query Resolution | Crystal Rowell (b) (4) | 11 Jan 2021 23:12:38 |

US3362244

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:14:58

Date of dosing discontinuation (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| User closed query 'PER DMR-Data is entered on dosing discontinuation form. but no data is updated on the End of study/study discontinuation form. Kindly verify and consider to update data accordingly. Thank you.' (Site from DM). | (b) (4), (b) (6) | 15 Oct 2020 07:21:36 |
| Query 'PER DMR-Data is entered on dosing discontinuation form. but no data is updated on the End of study/study discontinuation form. Kindly verify and consider to update data accordingly. Thank you.' answered with 'updated' (Site from DM). | (b) (4), (b) (6) | 14 Oct 2020 22:15:40 |
| User entered '23 Sep 2020' reason for change: Per Query Resolution | (b) (4), (b) (6) | 14 Oct 2020 22:15:37 |
| User opened query 'PER DMR-Data is entered on dosing discontinuation form. but no data is updated on the End of study/study discontinuation form. Kindly verify and consider to update data accordingly. Thank you.' (Site from DM). | (b) (4), (b) (6) | 14 Oct 2020 08:03:43 |
| User entered '15 Sep 2020' | (b) (4), (b) (6) | 08 Oct 2020 16:10:11 |

US3362244

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:14:58

[Primary reason for dosing discontinuation](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 12:59:55 |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| User entered 'AE (specify) (ADVERSE EVENT)' reason for change: Data Entry Error | Alexandra Caillouet (b) (4) | 25 Jan 2021 23:14:01 |
| User entered 'Other (OTHER)' reason for change: Data Entry Error | Alexandra Caillouet (b) (4) | 25 Jan 2021 23:05:40 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4), (b) (6) | 12 Jan 2021 17:46:03 |
| Query 'Data is required. Please complete.' answered with 'patient returned for unblinding and wanted dose' (Site from System). | Crystal Rowell (b) (4) | 11 Jan 2021 23:13:04 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 11 Jan 2021 23:12:38 |
| User entered empty; reason for change Data Entry Error | Crystal Rowell (b) (4) | 11 Jan 2021 23:12:38 |
| User entered 'AE (specify) (ADVERSE EVENT)' | (b) (4), (b) (6) | 08 Oct 2020 16:10:11 |

US3362244

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:14:58

If reason is AE, SAE, 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 12:59:55 |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| User closed query 'Per CDM: Per sponsor review, please update specify field to include only AE, number sign, and number. (i.e. AE #1).' (Site from DM). | (b) (4), (b) (6) | 08 Mar 2021 19:24:48 |
| Query 'Per CDM: Per sponsor review, please update specify field to include only AE, number sign, and number. (i.e. AE #1).' answered with 'updated per query ' (Site from DM). | Amy Thomassie (b) (4) | 06 Mar 2021 19:51:05 |
| User entered 'AE # 2, AE # 3, AND AE # 5' reason for change: Data Entry Error | Amy Thomassie (b) (4) | 06 Mar 2021 19:50:56 |
| User opened query 'Per CDM: Per sponsor review, please update specify field to include only AE, number sign, and number. (i.e. AE #1).' (Site from DM). | (b) (4), (b) (6) | 02 Mar 2021 19:42:42 |
| Query 'Per CDM: Per sponsor review, please update specify field to include both AE, number sign, and number. (i.e. AE #1).' canceled (Site from DM). | (b) (4), (b) (6) | 02 Mar 2021 19:42:28 |
| User opened query 'Per CDM: Per sponsor review, please update specify field to include both AE, number sign, and number. (i.e. AE #1).' (Site from DM). | (b) (4), (b) (6) | 02 Mar 2021 19:42:26 |
| Query 'Per CDM: Per sponsor review, please update specify field to include both AE, number sign, and number. (i.e. AE #2).' canceled (Site from DM). | (b) (4), (b) (6) | 02 Mar 2021 19:42:05 |
| User opened query 'Per CDM: Per sponsor review, please update specify field to include both AE, number sign, and number. (i.e. AE #2).' (Site from DM). | (b) (4), (b) (6) | 02 Mar 2021 19:41:46 |
| User closed query 'Per CDM: Please record the AE # log line that led to dosing discontinuation. Kindly reconcile with other applicable sections of the eCRF and update as needed, else provide clarification.' (Site from DM). | (b) (4), (b) (6) | 01 Feb 2021 06:11:22 |

US3362244

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:14:58

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

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Query 'Per CDM: Please record the AE # log line that led to dosing discontinuation. Kindly reconcile with other applicable sections of the eCRF and update as needed, else provide clarification.' answered with 'AE #s and names included.' (Site from DM). | Alexandra Caillouet (b) (4) | 29 Jan 2021 23:38:49 |
| User entered 'AE Log # 2, #3, and #5. Post-Op Intra-abdominal abscess Right Axillary DVT Right Brachial DVT' reason for change: Data Entry Error | Alexandra Caillouet (b) (4) | 29 Jan 2021 23:38:33 |
| User opened query 'Per CDM: Please record the AE # log line that led to dosing discontinuation. Kindly reconcile with other applicable sections of the eCRF and update as needed, else provide clarification.' (Site from DM). | (b) (4), (b) (6) | 27 Jan 2021 22:12:03 |
| User entered 'Subject complained of significant pain at injection site after the first visit. She declined 2nd injection at Visit 2 as she had surgery pre-planned the following week and was uncomfortable with shot.' reason for change: Data Entry Error | Alexandra Caillouet (b) (4) | 25 Jan 2021 23:05:40 |
| User entered empty; reason for change Data Entry Error | Crystal Rowell (b) (4) | 11 Jan 2021 23:12:38 |
| User closed query 'Per CDM: please record AE record number (i.e. AE #1, etc.) instead of details' (Site from DM). | (b) (4), (b) (6) | 19 Nov 2020 14:44:31 |
| Query 'Per CDM: please record AE record number (i.e. AE #1, etc.) instead of details' answered with 'updated ' (Site from DM). | Crystal Rowell (b) (4) | 18 Nov 2020 22:10:41 |
| User entered 'AE ID 1' reason for change: Data Entry Error | Crystal Rowell (b) (4) | 18 Nov 2020 22:10:31 |
| User opened query 'Per CDM: please record AE record number (i.e. AE #1, etc.) instead of details' (Site from DM). | (b) (4), (b) (6) | 18 Nov 2020 15:00:38 |
| User entered 'Worsening of Hip condition caused subject to refuse 2nd vaccine administration' | (b) (4), (b) (6) | 08 Oct 2020 16:10:11 |

US3362244

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:14:58

Date of study discontinuation/completion (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 12:59:55 |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| User closed query 'Per CDM: Please be aware that this form should not be completed because subject withdrawn only IP and not the study. Please consider removing data here. Thank you!' (Site from DM). | (b) (4) | 21 Oct 2020 07:46:02 |
| Query 'Per CDM: Please be aware that this form should not be completed because subject withdrawn only IP and not the study. Please consider removing data here. Thank you!' answered with 'data removed per query' (Site from DM). | (b) (4), (b) (6) | |
| User closed query 'Data is required. Please complete.' (Site from System). | Amy Thomassie (b) (4) | 21 Oct 2020 00:15:47 |
| User opened query 'Per CDM: Please be aware that this form should not be completed because subject withdrawn only IP and not the study. Please consider removing data here. Thank you!' (Site from DM). | (b) (4) | |
| Query 'Data is required. Please complete.' answered with 'Patient not completely withdrawn from study. Patient only withdrew consent from IP.' (Site from System). | (b) (4), (b) (6) | 20 Oct 2020 17:09:18 |
| User opened query 'Data is required. Please complete.' (Site from System). | (b) (4), (b) (6) | 20 Oct 2020 11:07:45 |
| User entered empty. | (b) (4), (b) (6) | 14 Oct 2020 22:22:35 |
| | System | 14 Oct 2020 22:19:46 |
| | (b) (4), (b) (6) | 14 Oct 2020 22:19:46 |

US3362244

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:14:58

[Reason for discontinuation](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 12:59:55 |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4) | 21 Oct 2020 07:46:03 |
| Query 'Data is required. Please complete.' answered with 'query above requested data be removed for now' (Site from System). | (b) (4), (b) (6) | 21 Oct 2020 00:16:03 |
| User opened query 'Data is required. Please complete.' (Site from System). | Amy Thomassie (b) (4) | 21 Oct 2020 00:16:03 |
| User entered empty; reason for change Data Entry Error | (b) (4) | 21 Oct 2020 00:15:10 |
| User closed query 'Death details are provided below, however Reason for Discontinuation is not Death. Please correct.' (Site from System). | System | 21 Oct 2020 00:15:10 |
| User opened query 'Death details are provided below, however Reason for Discontinuation is not Death. Please correct.' (Site from System). | Amy Thomassie (b) (4) | 21 Oct 2020 00:15:10 |
| User entered 'AE (specify) (ADVERSE EVENT)' | (b) (4) | 16 Oct 2020 21:20:24 |
| | System | 14 Oct 2020 22:19:46 |
| | System | 14 Oct 2020 22:19:46 |
| | System | 14 Oct 2020 22:19:46 |

US3362244

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:14:58

If reason is AE, SAE, 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 12:59:55 |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| User entered empty; reason for change Data Entry Error | Amy Thomassie (b) (4) | 21 Oct 2020 00:15:10 |
| User entered 'Patient having surgical procedure one week after 2nd injection was scheduled. Patient elected to withdraw IP and proceed with surgery. Patient only discontinued IP. She is still continuing in the study' | (b) (4), (b) (6) | 14 Oct 2020 22:19:46 |

US3362244

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:14:58

[If reason for discontinuation is Death, main cause of death](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 12:59:55 |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| User entered empty; reason for change Data Entry Error | Amy Thomassie (b) (4) | 16 Oct 2020 21:20:24 |
| User entered 'Adverse event (ADVERSE EVENT)' | (b) (4), (b) (6) | 14 Oct 2020 22:19:46 |

US3362244

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:14:58

[If main cause of death is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 12:59:55 |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| User entered empty. | (b) (4), (b) (6) | 14 Oct 2020 22:19:46 |

US3362244

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:14:58

Date of death (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 12:59:55 |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| User entered empty. | (b) (4), (b) (6) | 14 Oct 2020 22:19:46 |

US3362244

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:14:58

[Was autopsy performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 12:59:55 |
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| User entered empty. | (b) (4), (b) (6) | 14 Oct 2020 22:19:46 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[SAEID](#)

| Audit | User | Time (GMT) |
|---------------------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 29 Oct 2020 18:59:43 |
| User entered | | |
| 'USA-US112-2020-MRNA-1273-P301000006' | System | 29 Oct 2020 18:59:17 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

Serious

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 29 Oct 2020 18:59:43 |
| User entered 'Yes (Y)' | System | 29 Oct 2020 18:59:17 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 29 Oct 2020 18:59:43 |
| User entered 'No (N)' | System | 29 Oct 2020 18:59:17 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:21 |
| | | |
| Un-reviewed for Safety. | System | 02 Nov 2020 15:02:07 |
| User entered 'Yes (Y)' | System | 02 Nov 2020 15:02:07 |
| Reviewed for Safety. | (b) (4), (b) (6) | 29 Oct 2020 18:59:43 |
| | | |
| User entered 'No (N)' | System | 29 Oct 2020 18:59:17 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 29 Oct 2020 18:59:43 |
| User entered 'Yes (Y)' | System | 29 Oct 2020 18:59:17 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 29 Oct 2020 18:59:43 |
| User entered 'No (N)' | System | 29 Oct 2020 18:59:17 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 29 Oct 2020 18:59:43 |
| User entered 'No (N)' | System | 29 Oct 2020 18:59:17 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 29 Oct 2020 18:59:43 |
| User entered 'No (N)' | System | 29 Oct 2020 18:59:17 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 29 Oct 2020 18:59:43 |
| User entered 'Jordan' | System | 29 Oct 2020 18:59:17 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 29 Oct 2020 18:59:43 |
| User entered 'Whatley' | System | 29 Oct 2020 18:59:17 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 29 Oct 2020 18:59:43 |
| User entered '5326 O'donovan dr' | System | 29 Oct 2020 18:59:17 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Site Address: City](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 29 Oct 2020 18:59:43 |
| User entered 'baton rouge' | System | 29 Oct 2020 18:59:17 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

Site Address: [State](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:21 |
| | | |
| User entered empty. | System | 02 Nov 2020 15:02:07 |
| User entered '5326 O'Donovan Dr Baton Rouge, La 70808' | Crystal Rowell (b) (4) | 30 Oct 2020 18:54:16 |
| | (b) (4) | |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 29 Oct 2020 18:59:43 |
| User entered '70808' | System | 29 Oct 2020 18:59:17 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:21 |
| | | |
| User entered 'US' | System | 29 Oct 2020 18:59:53 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '5' | System | 07 Jan 2021 20:00:36 |
| User entered '4' | System | 15 Dec 2020 15:28:00 |
| User entered '3' | System | 11 Nov 2020 19:08:22 |
| User entered '2' | System | 02 Nov 2020 15:04:41 |
| User entered '1' | System | 29 Oct 2020 18:59:53 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[SAEID](#)

| Audit | User | Time (GMT) |
|---------------------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 29 Oct 2020 18:59:43 |
| User entered | | |
| 'USA-US112-2020-MRNA-1273-P301000006' | System | 29 Oct 2020 18:59:17 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

Serious

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 29 Oct 2020 18:59:43 |
| User entered 'Yes (Y)' | System | 29 Oct 2020 18:59:17 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 29 Oct 2020 18:59:43 |
| User entered 'No (N)' | System | 29 Oct 2020 18:59:17 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:21 |
| | | |
| Un-reviewed for Safety. | System | 02 Nov 2020 15:02:07 |
| User entered 'Yes (Y)' | System | 02 Nov 2020 15:02:07 |
| Reviewed for Safety. | (b) (4), (b) (6) | 29 Oct 2020 18:59:43 |
| | | |
| User entered 'No (N)' | System | 29 Oct 2020 18:59:17 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 29 Oct 2020 18:59:43 |
| User entered 'Yes (Y)' | System | 29 Oct 2020 18:59:17 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 29 Oct 2020 18:59:43 |
| User entered 'No (N)' | System | 29 Oct 2020 18:59:17 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 29 Oct 2020 18:59:43 |
| User entered 'No (N)' | System | 29 Oct 2020 18:59:17 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 29 Oct 2020 18:59:43 |
| User entered 'No (N)' | System | 29 Oct 2020 18:59:17 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 29 Oct 2020 18:59:43 |
| User entered 'Jordan' | System | 29 Oct 2020 18:59:17 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 29 Oct 2020 18:59:43 |
| User entered 'Whatley' | System | 29 Oct 2020 18:59:17 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 29 Oct 2020 18:59:43 |
| User entered '5326 O'donovan dr' | System | 29 Oct 2020 18:59:17 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Site Address: City](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 29 Oct 2020 18:59:43 |
| User entered 'baton rouge' | System | 29 Oct 2020 18:59:17 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

Site Address: [State](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:21 |
| | | |
| User entered empty. | System | 02 Nov 2020 15:02:07 |
| User entered '5326 O'Donovan Dr Baton Rouge, La 70808' | Crystal Rowell (b) (4) | 30 Oct 2020 18:54:16 |
| | (b) (4) | |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 29 Oct 2020 18:59:43 |
| User entered '70808' | System | 29 Oct 2020 18:59:17 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:21 |
| | | |
| User entered 'US' | System | 29 Oct 2020 18:59:53 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '5' | System | 07 Jan 2021 20:00:36 |
| User entered '4' | System | 15 Dec 2020 15:28:00 |
| User entered '3' | System | 11 Nov 2020 19:08:22 |
| User entered '2' | System | 02 Nov 2020 15:04:41 |
| User entered '1' | System | 29 Oct 2020 18:59:53 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:14:58

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| User entered '29/Oct/2020 18:59' | System | 29 Oct 2020 18:59:53 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:14:58

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. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) (d) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| Reviewed for Safety. | | 02 Nov 2020 15:04:21 |
| User entered 'I' | | 29 Oct 2020 18:59:53 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[SAEID](#)

| Audit | User | Time (GMT) |
|---------------------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 29 Oct 2020 18:59:43 |
| User entered | | |
| 'USA-US112-2020-MRNA-1273-P301000006' | System | 29 Oct 2020 18:59:17 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

Serious

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 29 Oct 2020 18:59:43 |
| User entered 'Yes (Y)' | System | 29 Oct 2020 18:59:17 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 29 Oct 2020 18:59:43 |
| User entered 'No (N)' | System | 29 Oct 2020 18:59:17 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:21 |
| | | |
| Un-reviewed for Safety. | System | 02 Nov 2020 15:02:07 |
| User entered 'Yes (Y)' | System | 02 Nov 2020 15:02:07 |
| Reviewed for Safety. | (b) (4), (b) (6) | 29 Oct 2020 18:59:43 |
| | | |
| User entered 'No (N)' | System | 29 Oct 2020 18:59:17 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 29 Oct 2020 18:59:43 |
| User entered 'Yes (Y)' | System | 29 Oct 2020 18:59:17 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 29 Oct 2020 18:59:43 |
| User entered 'No (N)' | System | 29 Oct 2020 18:59:17 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 29 Oct 2020 18:59:43 |
| User entered 'No (N)' | System | 29 Oct 2020 18:59:17 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 29 Oct 2020 18:59:43 |
| User entered 'No (N)' | System | 29 Oct 2020 18:59:17 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 29 Oct 2020 18:59:43 |
| User entered 'Jordan' | System | 29 Oct 2020 18:59:17 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 29 Oct 2020 18:59:43 |
| User entered 'Whatley' | System | 29 Oct 2020 18:59:17 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 29 Oct 2020 18:59:43 |
| User entered '5326 O'donovan dr' | System | 29 Oct 2020 18:59:17 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Site Address: City](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 29 Oct 2020 18:59:43 |
| User entered 'baton rouge' | System | 29 Oct 2020 18:59:17 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Site Address: State](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:21 |
| | | |
| User entered empty. | System | 02 Nov 2020 15:02:07 |
| User entered '5326 O'Donovan Dr Baton Rouge, La 70808' | Crystal Rowell (b) (4) | 30 Oct 2020 18:54:16 |
| | (b) (4) | |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 29 Oct 2020 18:59:43 |
| User entered '70808' | System | 29 Oct 2020 18:59:17 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:21 |
| | | |
| User entered 'US' | System | 29 Oct 2020 18:59:53 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '5' | System | 07 Jan 2021 20:00:36 |
| User entered '4' | System | 15 Dec 2020 15:28:00 |
| User entered '3' | System | 11 Nov 2020 19:08:22 |
| User entered '2' | System | 02 Nov 2020 15:04:41 |
| User entered '1' | System | 29 Oct 2020 18:59:53 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:14:58

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| User entered '30/Oct/2020 13:55' | Crystal Rowell (b) (4) (b) (4) | 30 Oct 2020 18:55:19 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:14:58

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. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 19:07:59 |
| DataPoint Verified. | | 05 Nov 2020 17:55:26 |
| User entered '0' | | 02 Nov 2020 15:04:41 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[SAEID](#)

| Audit | User | Time (GMT) |
|---------------------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 29 Oct 2020 18:59:43 |
| User entered | | |
| 'USA-US112-2020-MRNA-1273-P301000006' | System | 29 Oct 2020 18:59:17 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

Serious

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 29 Oct 2020 18:59:43 |
| User entered 'Yes (Y)' | System | 29 Oct 2020 18:59:17 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 29 Oct 2020 18:59:43 |
| User entered 'No (N)' | System | 29 Oct 2020 18:59:17 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:21 |
| | | |
| Un-reviewed for Safety. | System | 02 Nov 2020 15:02:07 |
| User entered 'Yes (Y)' | System | 02 Nov 2020 15:02:07 |
| Reviewed for Safety. | (b) (4), (b) (6) | 29 Oct 2020 18:59:43 |
| | | |
| User entered 'No (N)' | System | 29 Oct 2020 18:59:17 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 29 Oct 2020 18:59:43 |
| User entered 'Yes (Y)' | System | 29 Oct 2020 18:59:17 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 29 Oct 2020 18:59:43 |
| User entered 'No (N)' | System | 29 Oct 2020 18:59:17 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 29 Oct 2020 18:59:43 |
| User entered 'No (N)' | System | 29 Oct 2020 18:59:17 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 29 Oct 2020 18:59:43 |
| User entered 'No (N)' | System | 29 Oct 2020 18:59:17 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 29 Oct 2020 18:59:43 |
| User entered 'Jordan' | System | 29 Oct 2020 18:59:17 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 29 Oct 2020 18:59:43 |
| User entered 'Whatley' | System | 29 Oct 2020 18:59:17 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 29 Oct 2020 18:59:43 |
| User entered '5326 O'donovan dr' | System | 29 Oct 2020 18:59:17 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Site Address: City](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 29 Oct 2020 18:59:43 |
| User entered 'baton rouge' | System | 29 Oct 2020 18:59:17 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Site Address: State](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:21 |
| | | |
| User entered empty. | System | 02 Nov 2020 15:02:07 |
| User entered '5326 O'Donovan Dr Baton Rouge, La 70808' | Crystal Rowell (b) (4) | 30 Oct 2020 18:54:16 |
| | (b) (4) | |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 29 Oct 2020 18:59:43 |
| User entered '70808' | System | 29 Oct 2020 18:59:17 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:21 |
| | | |
| User entered 'US' | System | 29 Oct 2020 18:59:53 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '5' | System | 07 Jan 2021 20:00:36 |
| User entered '4' | System | 15 Dec 2020 15:28:00 |
| User entered '3' | System | 11 Nov 2020 19:08:22 |
| User entered '2' | System | 02 Nov 2020 15:04:41 |
| User entered '1' | System | 29 Oct 2020 18:59:53 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:14:58

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| User entered '02/Nov/2020 10:04' | System | 02 Nov 2020 15:04:41 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:14:58

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. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 19:07:59 |
| DataPoint Verified. | | 05 Nov 2020 17:55:26 |
| User entered 'I' | | 02 Nov 2020 15:04:41 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[SAEID](#)

| Audit | User | Time (GMT) |
|---------------------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 29 Oct 2020 18:59:43 |
| User entered | | |
| 'USA-US112-2020-MRNA-1273-P301000006' | System | 29 Oct 2020 18:59:17 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

Serious

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 29 Oct 2020 18:59:43 |
| User entered 'Yes (Y)' | System | 29 Oct 2020 18:59:17 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 29 Oct 2020 18:59:43 |
| User entered 'No (N)' | System | 29 Oct 2020 18:59:17 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:21 |
| | | |
| Un-reviewed for Safety. | System | 02 Nov 2020 15:02:07 |
| User entered 'Yes (Y)' | System | 02 Nov 2020 15:02:07 |
| Reviewed for Safety. | (b) (4), (b) (6) | 29 Oct 2020 18:59:43 |
| | | |
| User entered 'No (N)' | System | 29 Oct 2020 18:59:17 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 29 Oct 2020 18:59:43 |
| User entered 'Yes (Y)' | System | 29 Oct 2020 18:59:17 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 29 Oct 2020 18:59:43 |
| User entered 'No (N)' | System | 29 Oct 2020 18:59:17 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 29 Oct 2020 18:59:43 |
| User entered 'No (N)' | System | 29 Oct 2020 18:59:17 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 29 Oct 2020 18:59:43 |
| User entered 'No (N)' | System | 29 Oct 2020 18:59:17 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 29 Oct 2020 18:59:43 |
| User entered 'Jordan' | System | 29 Oct 2020 18:59:17 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 29 Oct 2020 18:59:43 |
| User entered 'Whatley' | System | 29 Oct 2020 18:59:17 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 29 Oct 2020 18:59:43 |
| User entered '5326 O'donovan dr' | System | 29 Oct 2020 18:59:17 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Site Address: City](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 29 Oct 2020 18:59:43 |
| User entered 'baton rouge' | System | 29 Oct 2020 18:59:17 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

Site Address: State

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:21 |
| | | |
| User entered empty. | System | 02 Nov 2020 15:02:07 |
| User entered '5326 O'Donovan Dr Baton Rouge, La 70808' | Crystal Rowell (b) (4) | 30 Oct 2020 18:54:16 |
| | (b) (4) | |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 29 Oct 2020 18:59:43 |
| User entered '70808' | System | 29 Oct 2020 18:59:17 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:21 |
| | | |
| User entered 'US' | System | 29 Oct 2020 18:59:53 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '5' | System | 07 Jan 2021 20:00:36 |
| User entered '4' | System | 15 Dec 2020 15:28:00 |
| User entered '3' | System | 11 Nov 2020 19:08:22 |
| User entered '2' | System | 02 Nov 2020 15:04:41 |
| User entered '1' | System | 29 Oct 2020 18:59:53 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:14:58

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| User entered '11/Nov/2020 19:08' | (b) (4) System | 11 Nov 2020 19:08:22 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:14:58

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. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 15 Dec 2020 15:27:29 |
| User entered 'I' | (b) (4), (b) (6) | 11 Nov 2020 19:08:22 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[SAEID](#)

| Audit | User | Time (GMT) |
|---------------------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 29 Oct 2020 18:59:43 |
| User entered | | |
| 'USA-US112-2020-MRNA-1273-P301000006' | System | 29 Oct 2020 18:59:17 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

Serious

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 29 Oct 2020 18:59:43 |
| User entered 'Yes (Y)' | System | 29 Oct 2020 18:59:17 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 29 Oct 2020 18:59:43 |
| User entered 'No (N)' | System | 29 Oct 2020 18:59:17 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:21 |
| | | |
| Un-reviewed for Safety. | System | 02 Nov 2020 15:02:07 |
| User entered 'Yes (Y)' | System | 02 Nov 2020 15:02:07 |
| Reviewed for Safety. | (b) (4), (b) (6) | 29 Oct 2020 18:59:43 |
| | | |
| User entered 'No (N)' | System | 29 Oct 2020 18:59:17 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 29 Oct 2020 18:59:43 |
| User entered 'Yes (Y)' | System | 29 Oct 2020 18:59:17 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 29 Oct 2020 18:59:43 |
| User entered 'No (N)' | System | 29 Oct 2020 18:59:17 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 29 Oct 2020 18:59:43 |
| User entered 'No (N)' | System | 29 Oct 2020 18:59:17 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 29 Oct 2020 18:59:43 |
| User entered 'No (N)' | System | 29 Oct 2020 18:59:17 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 29 Oct 2020 18:59:43 |
| User entered 'Jordan' | System | 29 Oct 2020 18:59:17 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 29 Oct 2020 18:59:43 |
| User entered 'Whatley' | System | 29 Oct 2020 18:59:17 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 29 Oct 2020 18:59:43 |
| User entered '5326 O'donovan dr' | System | 29 Oct 2020 18:59:17 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Site Address: City](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 29 Oct 2020 18:59:43 |
| User entered 'baton rouge' | System | 29 Oct 2020 18:59:17 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

Site Address: [State](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:21 |
| | | |
| User entered empty. | System | 02 Nov 2020 15:02:07 |
| User entered '5326 O'Donovan Dr Baton Rouge, La 70808' | Crystal Rowell (b) (4) | 30 Oct 2020 18:54:16 |
| | (b) (4) | |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 29 Oct 2020 18:59:43 |
| User entered '70808' | System | 29 Oct 2020 18:59:17 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:21 |
| | | |
| User entered 'US' | System | 29 Oct 2020 18:59:53 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '5' | System | 07 Jan 2021 20:00:36 |
| User entered '4' | System | 15 Dec 2020 15:28:00 |
| User entered '3' | System | 11 Nov 2020 19:08:22 |
| User entered '2' | System | 02 Nov 2020 15:04:41 |
| User entered '1' | System | 29 Oct 2020 18:59:53 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:14:58

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| User entered '15/Dec/2020 10:27' | (b) (4) System | 15 Dec 2020 15:28:00 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:14:58

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. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| Reviewed for Safety. | (b) (4) | |
| | (b) (4), (b) (6) | 07 Jan 2021 20:00:17 |
| User entered 'I' | (b) (4), (b) (6) | 15 Dec 2020 15:28:00 |
| | | |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[SAEID](#)

| Audit | User | Time (GMT) |
|---------------------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 29 Oct 2020 18:59:43 |
| User entered | | |
| 'USA-US112-2020-MRNA-1273-P301000006' | System | 29 Oct 2020 18:59:17 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

Serious

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 29 Oct 2020 18:59:43 |
| User entered 'Yes (Y)' | System | 29 Oct 2020 18:59:17 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 29 Oct 2020 18:59:43 |
| User entered 'No (N)' | System | 29 Oct 2020 18:59:17 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:21 |
| | | |
| Un-reviewed for Safety. | System | 02 Nov 2020 15:02:07 |
| User entered 'Yes (Y)' | System | 02 Nov 2020 15:02:07 |
| Reviewed for Safety. | (b) (4), (b) (6) | 29 Oct 2020 18:59:43 |
| | | |
| User entered 'No (N)' | System | 29 Oct 2020 18:59:17 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 29 Oct 2020 18:59:43 |
| User entered 'Yes (Y)' | System | 29 Oct 2020 18:59:17 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 29 Oct 2020 18:59:43 |
| User entered 'No (N)' | System | 29 Oct 2020 18:59:17 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 29 Oct 2020 18:59:43 |
| User entered 'No (N)' | System | 29 Oct 2020 18:59:17 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 29 Oct 2020 18:59:43 |
| User entered 'No (N)' | System | 29 Oct 2020 18:59:17 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 29 Oct 2020 18:59:43 |
| User entered 'Jordan' | System | 29 Oct 2020 18:59:17 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 29 Oct 2020 18:59:43 |
| User entered 'Whatley' | System | 29 Oct 2020 18:59:17 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 29 Oct 2020 18:59:43 |
| User entered '5326 O'donovan dr' | System | 29 Oct 2020 18:59:17 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Site Address: City](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 29 Oct 2020 18:59:43 |
| User entered 'baton rouge' | System | 29 Oct 2020 18:59:17 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

Site Address: State

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:21 |
| | | |
| User entered empty. | System | 02 Nov 2020 15:02:07 |
| User entered '5326 O'Donovan Dr Baton Rouge, La 70808' | Crystal Rowell (b) (4) | 30 Oct 2020 18:54:16 |
| | (b) (4) | |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 29 Oct 2020 18:59:43 |
| User entered '70808' | System | 29 Oct 2020 18:59:17 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:21 |
| | | |
| User entered 'US' | System | 29 Oct 2020 18:59:53 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '5' | System | 07 Jan 2021 20:00:36 |
| User entered '4' | System | 15 Dec 2020 15:28:00 |
| User entered '3' | System | 11 Nov 2020 19:08:22 |
| User entered '2' | System | 02 Nov 2020 15:04:41 |
| User entered '1' | System | 29 Oct 2020 18:59:53 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 17:14:58

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| User entered '07/Jan/2021 20:00' | (b) (4) System | 07 Jan 2021 20:00:36 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000006

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 17:14:58

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. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| User entered 'I' | (b) (4) (b) (4), (b) (6) | 07 Jan 2021 20:00:36 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[SAEID](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:47 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:50 |
| | | |
| User entered 'USA-US112-2020-MRNA-1273-P301000007' | System | 02 Nov 2020 15:03:44 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

Serious

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:47 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:50 |
| | | |
| User entered 'Yes (Y)' | System | 02 Nov 2020 15:03:44 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:47 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:50 |
| | | |
| User entered 'No (N)' | System | 02 Nov 2020 15:03:44 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:47 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:50 |
| | | |
| User entered 'No (N)' | System | 02 Nov 2020 15:03:44 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:47 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:50 |
| | | |
| User entered 'Yes (Y)' | System | 02 Nov 2020 15:03:44 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:47 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:50 |
| | | |
| User entered 'No (N)' | System | 02 Nov 2020 15:03:44 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:47 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:50 |
| | | |
| User entered 'No (N)' | System | 02 Nov 2020 15:03:44 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:47 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:50 |
| | | |
| User entered 'No (N)' | System | 02 Nov 2020 15:03:44 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:47 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:50 |
| | | |
| User entered 'Jordan' | System | 02 Nov 2020 15:03:44 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:47 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:50 |
| | | |
| User entered 'Whatley' | System | 02 Nov 2020 15:03:44 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:47 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:50 |
| | | |
| User entered '5326 O'donovan dr' | System | 02 Nov 2020 15:03:44 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Site Address: City](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:47 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:50 |
| | | |
| User entered 'baton rouge' | System | 02 Nov 2020 15:03:44 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

Site Address: State

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| Reviewed for Safety. | (b) (4) | |
| | (b) (4), (b) (6) | 11 Nov 2020 20:31:16 |
| Un-reviewed for Safety. | System | 10 Nov 2020 16:32:26 |
| User entered empty. | System | 10 Nov 2020 16:32:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Nov 2020 16:31:52 |
| | | |
| User entered 'Louisiana' | Crystal Rowell (b) (4) | 09 Nov 2020 22:01:36 |
| | (b) (4) | |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:47 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:50 |
| | | |
| User entered '70808' | System | 02 Nov 2020 15:03:44 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:47 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:50 |
| | | |
| User entered 'US' | System | 02 Nov 2020 15:04:41 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '6' | System | 16 Dec 2020 19:55:25 |
| User entered '5' | System | 20 Nov 2020 19:29:01 |
| User entered '4' | System | 13 Nov 2020 13:41:36 |
| User entered '3' | System | 11 Nov 2020 20:31:36 |
| User entered '2' | System | 10 Nov 2020 16:32:26 |
| User entered '1' | System | 02 Nov 2020 15:05:02 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[SAEID](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:47 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:50 |
| | | |
| User entered 'USA-US112-2020-MRNA-1273-P301000007' | System | 02 Nov 2020 15:03:44 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

Serious

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:47 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:50 |
| | | |
| User entered 'Yes (Y)' | System | 02 Nov 2020 15:03:44 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:47 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:50 |
| | | |
| User entered 'No (N)' | System | 02 Nov 2020 15:03:44 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:47 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:50 |
| | | |
| User entered 'No (N)' | System | 02 Nov 2020 15:03:44 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:47 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:50 |
| | | |
| User entered 'Yes (Y)' | System | 02 Nov 2020 15:03:44 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:47 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:50 |
| | | |
| User entered 'No (N)' | System | 02 Nov 2020 15:03:44 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:47 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:50 |
| | | |
| User entered 'No (N)' | System | 02 Nov 2020 15:03:44 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:47 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:50 |
| | | |
| User entered 'No (N)' | System | 02 Nov 2020 15:03:44 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:47 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:50 |
| | | |
| User entered 'Jordan' | System | 02 Nov 2020 15:03:44 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:47 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:50 |
| | | |
| User entered 'Whatley' | System | 02 Nov 2020 15:03:44 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:47 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:50 |
| | | |
| User entered '5326 O'donovan dr' | System | 02 Nov 2020 15:03:44 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Site Address: City](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:47 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:50 |
| | | |
| User entered 'baton rouge' | System | 02 Nov 2020 15:03:44 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Site Address: State](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| Reviewed for Safety. | (b) (4) | |
| | (b) (4), (b) (6) | 11 Nov 2020 20:31:16 |
| Un-reviewed for Safety. | System | 10 Nov 2020 16:32:26 |
| User entered empty. | System | 10 Nov 2020 16:32:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Nov 2020 16:31:52 |
| | | |
| User entered 'Louisiana' | Crystal Rowell (b) (4) | 09 Nov 2020 22:01:36 |
| | (b) (4) | |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:47 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:50 |
| | | |
| User entered '70808' | System | 02 Nov 2020 15:03:44 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:47 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:50 |
| | | |
| User entered 'US' | System | 02 Nov 2020 15:04:41 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '6' | System | 16 Dec 2020 19:55:25 |
| User entered '5' | System | 20 Nov 2020 19:29:01 |
| User entered '4' | System | 13 Nov 2020 13:41:36 |
| User entered '3' | System | 11 Nov 2020 20:31:36 |
| User entered '2' | System | 10 Nov 2020 16:32:26 |
| User entered '1' | System | 02 Nov 2020 15:05:02 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:14:58

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 05 Nov 2020 17:55:47 |
| User entered '02/Nov/2020 10:04' | System | 02 Nov 2020 15:05:02 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:14:58

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. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 10 Nov 2020 16:31:52 |
| DataPoint Verified. | | 05 Nov 2020 17:55:47 |
| User entered 'I' | | 02 Nov 2020 15:05:02 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[SAEID](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:47 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:50 |
| | | |
| User entered 'USA-US112-2020-MRNA-1273-P301000007' | System | 02 Nov 2020 15:03:44 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

Serious

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:47 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:50 |
| | | |
| User entered 'Yes (Y)' | System | 02 Nov 2020 15:03:44 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:47 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:50 |
| | | |
| User entered 'No (N)' | System | 02 Nov 2020 15:03:44 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:47 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:50 |
| | | |
| User entered 'No (N)' | System | 02 Nov 2020 15:03:44 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:47 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:50 |
| | | |
| User entered 'Yes (Y)' | System | 02 Nov 2020 15:03:44 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:47 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:50 |
| | | |
| User entered 'No (N)' | System | 02 Nov 2020 15:03:44 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:47 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:50 |
| | | |
| User entered 'No (N)' | System | 02 Nov 2020 15:03:44 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:47 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:50 |
| | | |
| User entered 'No (N)' | System | 02 Nov 2020 15:03:44 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:47 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:50 |
| | | |
| User entered 'Jordan' | System | 02 Nov 2020 15:03:44 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:47 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:50 |
| | | |
| User entered 'Whatley' | System | 02 Nov 2020 15:03:44 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:47 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:50 |
| | | |
| User entered '5326 O'donovan dr' | System | 02 Nov 2020 15:03:44 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Site Address: City](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:47 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:50 |
| | | |
| User entered 'baton rouge' | System | 02 Nov 2020 15:03:44 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

Site Address: State

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| Reviewed for Safety. | (b) (4) | |
| | (b) (4), (b) (6) | 11 Nov 2020 20:31:16 |
| Un-reviewed for Safety. | System | 10 Nov 2020 16:32:26 |
| User entered empty. | System | 10 Nov 2020 16:32:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Nov 2020 16:31:52 |
| | | |
| User entered 'Louisiana' | Crystal Rowell (b) (4) | 09 Nov 2020 22:01:36 |
| | (b) (4) | |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:47 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:50 |
| | | |
| User entered '70808' | System | 02 Nov 2020 15:03:44 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:47 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:50 |
| | | |
| User entered 'US' | System | 02 Nov 2020 15:04:41 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '6' | System | 16 Dec 2020 19:55:25 |
| User entered '5' | System | 20 Nov 2020 19:29:01 |
| User entered '4' | System | 13 Nov 2020 13:41:36 |
| User entered '3' | System | 11 Nov 2020 20:31:36 |
| User entered '2' | System | 10 Nov 2020 16:32:26 |
| User entered '1' | System | 02 Nov 2020 15:05:02 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:14:58

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| User entered '10/Nov/2020 11:32' | (b) (4) System | 10 Nov 2020 16:32:26 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:14:58

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. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| Reviewed for Safety. | (b) (4) | |
| | (b) (4), (b) (6) | 11 Nov 2020 20:31:16 |
| User entered 'I' | (b) (4), (b) (6) | 10 Nov 2020 16:32:26 |
| | | |
| | | |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[SAEID](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:47 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:50 |
| | | |
| User entered 'USA-US112-2020-MRNA-1273-P301000007' | System | 02 Nov 2020 15:03:44 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

Serious

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:47 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:50 |
| | | |
| User entered 'Yes (Y)' | System | 02 Nov 2020 15:03:44 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:47 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:50 |
| | | |
| User entered 'No (N)' | System | 02 Nov 2020 15:03:44 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:47 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:50 |
| | | |
| User entered 'No (N)' | System | 02 Nov 2020 15:03:44 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:47 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:50 |
| | | |
| User entered 'Yes (Y)' | System | 02 Nov 2020 15:03:44 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:47 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:50 |
| | | |
| User entered 'No (N)' | System | 02 Nov 2020 15:03:44 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:47 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:50 |
| | | |
| User entered 'No (N)' | System | 02 Nov 2020 15:03:44 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:47 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:50 |
| | | |
| User entered 'No (N)' | System | 02 Nov 2020 15:03:44 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:47 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:50 |
| | | |
| User entered 'Jordan' | System | 02 Nov 2020 15:03:44 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:47 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:50 |
| | | |
| User entered 'Whatley' | System | 02 Nov 2020 15:03:44 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:47 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:50 |
| | | |
| User entered '5326 O'donovan dr' | System | 02 Nov 2020 15:03:44 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Site Address: City](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:47 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:50 |
| | | |
| User entered 'baton rouge' | System | 02 Nov 2020 15:03:44 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

Site Address: State

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| Reviewed for Safety. | (b) (4) | |
| | (b) (4), (b) (6) | 11 Nov 2020 20:31:16 |
| Un-reviewed for Safety. | System | 10 Nov 2020 16:32:26 |
| User entered empty. | System | 10 Nov 2020 16:32:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Nov 2020 16:31:52 |
| | | |
| User entered 'Louisiana' | Crystal Rowell (b) (4) | 09 Nov 2020 22:01:36 |
| | (b) (4) | |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:47 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:50 |
| | | |
| User entered '70808' | System | 02 Nov 2020 15:03:44 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:47 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:50 |
| | | |
| User entered 'US' | System | 02 Nov 2020 15:04:41 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '6' | System | 16 Dec 2020 19:55:25 |
| User entered '5' | System | 20 Nov 2020 19:29:01 |
| User entered '4' | System | 13 Nov 2020 13:41:36 |
| User entered '3' | System | 11 Nov 2020 20:31:36 |
| User entered '2' | System | 10 Nov 2020 16:32:26 |
| User entered '1' | System | 02 Nov 2020 15:05:02 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:14:58

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| User entered '11/Nov/2020 20:31' | (b) (4) System | 11 Nov 2020 20:31:36 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:14:58

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. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| Reviewed for Safety. | (b) (4) | |
| | (b) (4), (b) (6) | 13 Nov 2020 13:41:17 |
| User entered 'I' | (b) (4), (b) (6) | 11 Nov 2020 20:31:36 |
| | | |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[SAEID](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:47 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:50 |
| | | |
| User entered 'USA-US112-2020-MRNA-1273-P301000007' | System | 02 Nov 2020 15:03:44 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

Serious

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:47 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:50 |
| | | |
| User entered 'Yes (Y)' | System | 02 Nov 2020 15:03:44 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:47 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:50 |
| | | |
| User entered 'No (N)' | System | 02 Nov 2020 15:03:44 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:47 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:50 |
| | | |
| User entered 'No (N)' | System | 02 Nov 2020 15:03:44 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:47 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:50 |
| | | |
| User entered 'Yes (Y)' | System | 02 Nov 2020 15:03:44 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:47 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:50 |
| | | |
| User entered 'No (N)' | System | 02 Nov 2020 15:03:44 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:47 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:50 |
| | | |
| User entered 'No (N)' | System | 02 Nov 2020 15:03:44 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:47 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:50 |
| | | |
| User entered 'No (N)' | System | 02 Nov 2020 15:03:44 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:47 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:50 |
| | | |
| User entered 'Jordan' | System | 02 Nov 2020 15:03:44 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:47 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:50 |
| | | |
| User entered 'Whatley' | System | 02 Nov 2020 15:03:44 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:47 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:50 |
| | | |
| User entered '5326 O'donovan dr' | System | 02 Nov 2020 15:03:44 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Site Address: City](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:47 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:50 |
| | | |
| User entered 'baton rouge' | System | 02 Nov 2020 15:03:44 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Site Address: State](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| Reviewed for Safety. | (b) (4) | |
| | (b) (4), (b) (6) | 11 Nov 2020 20:31:16 |
| Un-reviewed for Safety. | System | 10 Nov 2020 16:32:26 |
| User entered empty. | System | 10 Nov 2020 16:32:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Nov 2020 16:31:52 |
| | | |
| User entered 'Louisiana' | Crystal Rowell (b) (4) | 09 Nov 2020 22:01:36 |
| | (b) (4) | |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:47 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:50 |
| | | |
| User entered '70808' | System | 02 Nov 2020 15:03:44 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:47 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:50 |
| | | |
| User entered 'US' | System | 02 Nov 2020 15:04:41 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '6' | System | 16 Dec 2020 19:55:25 |
| User entered '5' | System | 20 Nov 2020 19:29:01 |
| User entered '4' | System | 13 Nov 2020 13:41:36 |
| User entered '3' | System | 11 Nov 2020 20:31:36 |
| User entered '2' | System | 10 Nov 2020 16:32:26 |
| User entered '1' | System | 02 Nov 2020 15:05:02 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:14:58

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| User entered '13/Nov/2020 13:41' | (b) (4) System | 13 Nov 2020 13:41:36 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:14:58

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. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| Reviewed for Safety. | (b) (4) | |
| | (b) (4), (b) (6) | 20 Nov 2020 19:28:22 |
| User entered 'I' | (b) (4), (b) (6) | 13 Nov 2020 13:41:36 |
| | | |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[SAEID](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:47 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:50 |
| | | |
| User entered 'USA-US112-2020-MRNA-1273-P301000007' | System | 02 Nov 2020 15:03:44 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

Serious

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:47 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:50 |
| | | |
| User entered 'Yes (Y)' | System | 02 Nov 2020 15:03:44 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:47 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:50 |
| | | |
| User entered 'No (N)' | System | 02 Nov 2020 15:03:44 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:47 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:50 |
| | | |
| User entered 'No (N)' | System | 02 Nov 2020 15:03:44 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:47 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:50 |
| | | |
| User entered 'Yes (Y)' | System | 02 Nov 2020 15:03:44 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:47 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:50 |
| | | |
| User entered 'No (N)' | System | 02 Nov 2020 15:03:44 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:47 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:50 |
| | | |
| User entered 'No (N)' | System | 02 Nov 2020 15:03:44 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:47 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:50 |
| | | |
| User entered 'No (N)' | System | 02 Nov 2020 15:03:44 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:47 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:50 |
| | | |
| User entered 'Jordan' | System | 02 Nov 2020 15:03:44 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:47 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:50 |
| | | |
| User entered 'Whatley' | System | 02 Nov 2020 15:03:44 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:47 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:50 |
| | | |
| User entered '5326 O'donovan dr' | System | 02 Nov 2020 15:03:44 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Site Address: City](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:47 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:50 |
| | | |
| User entered 'baton rouge' | System | 02 Nov 2020 15:03:44 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Site Address: State](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| Reviewed for Safety. | (b) (4) | |
| | (b) (4), (b) (6) | 11 Nov 2020 20:31:16 |
| Un-reviewed for Safety. | System | 10 Nov 2020 16:32:26 |
| User entered empty. | System | 10 Nov 2020 16:32:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Nov 2020 16:31:52 |
| | | |
| User entered 'Louisiana' | Crystal Rowell (b) (4) | 09 Nov 2020 22:01:36 |
| | (b) (4) | |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:47 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:50 |
| | | |
| User entered '70808' | System | 02 Nov 2020 15:03:44 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:47 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:50 |
| | | |
| User entered 'US' | System | 02 Nov 2020 15:04:41 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '6' | System | 16 Dec 2020 19:55:25 |
| User entered '5' | System | 20 Nov 2020 19:29:01 |
| User entered '4' | System | 13 Nov 2020 13:41:36 |
| User entered '3' | System | 11 Nov 2020 20:31:36 |
| User entered '2' | System | 10 Nov 2020 16:32:26 |
| User entered '1' | System | 02 Nov 2020 15:05:02 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:14:58

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| User entered '20/Nov/2020 19:28' | (b) (4) System | 20 Nov 2020 19:29:01 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:14:58

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. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| User entered 'I' | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 19:29:01 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[SAEID](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:47 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:50 |
| | | |
| User entered 'USA-US112-2020-MRNA-1273-P301000007' | System | 02 Nov 2020 15:03:44 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

Serious

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:47 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:50 |
| | | |
| User entered 'Yes (Y)' | System | 02 Nov 2020 15:03:44 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:47 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:50 |
| | | |
| User entered 'No (N)' | System | 02 Nov 2020 15:03:44 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:47 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:50 |
| | | |
| User entered 'No (N)' | System | 02 Nov 2020 15:03:44 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:47 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:50 |
| | | |
| User entered 'Yes (Y)' | System | 02 Nov 2020 15:03:44 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:47 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:50 |
| | | |
| User entered 'No (N)' | System | 02 Nov 2020 15:03:44 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:47 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:50 |
| | | |
| User entered 'No (N)' | System | 02 Nov 2020 15:03:44 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:47 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:50 |
| | | |
| User entered 'No (N)' | System | 02 Nov 2020 15:03:44 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:47 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:50 |
| | | |
| User entered 'Jordan' | System | 02 Nov 2020 15:03:44 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:47 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:50 |
| | | |
| User entered 'Whatley' | System | 02 Nov 2020 15:03:44 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:47 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:50 |
| | | |
| User entered '5326 O'donovan dr' | System | 02 Nov 2020 15:03:44 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Site Address: City](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:47 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:50 |
| | | |
| User entered 'baton rouge' | System | 02 Nov 2020 15:03:44 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

Site Address: State

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| Reviewed for Safety. | (b) (4) | |
| | (b) (4), (b) (6) | 11 Nov 2020 20:31:16 |
| Un-reviewed for Safety. | System | 10 Nov 2020 16:32:26 |
| User entered empty. | System | 10 Nov 2020 16:32:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Nov 2020 16:31:52 |
| | | |
| User entered 'Louisiana' | Crystal Rowell (b) (4) | 09 Nov 2020 22:01:36 |
| | (b) (4) | |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:47 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:50 |
| | | |
| User entered '70808' | System | 02 Nov 2020 15:03:44 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 05 Nov 2020 17:55:47 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Nov 2020 15:04:50 |
| | | |
| User entered 'US' | System | 02 Nov 2020 15:04:41 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:58

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '6' | System | 16 Dec 2020 19:55:25 |
| User entered '5' | System | 20 Nov 2020 19:29:01 |
| User entered '4' | System | 13 Nov 2020 13:41:36 |
| User entered '3' | System | 11 Nov 2020 20:31:36 |
| User entered '2' | System | 10 Nov 2020 16:32:26 |
| User entered '1' | System | 02 Nov 2020 15:05:02 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 17:14:58

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------------|----------------------|
| User signature succeeded. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| User entered '16/Dec/2020 13:55' | (b) (4) System | 16 Dec 2020 19:55:25 |

US3362244

Folder: SAE USA-US112-2020-MRNA-1273-P301000007

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 17:14:58

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. | Jordan Whatley (b) (4) | 25 Apr 2021 01:32:37 |
| User entered 'I' | (b) (4) (b) (4), (b) (6) | 16 Dec 2020 19:55:25 |