

US3062128 (Prod: Alliance for Multispecialty Research, LLC)

Generated By: KC Joubran

Generated On: 09 Jun 2021 15:03:08

All time stamps listed in this document are displayed in GMT

US3062128

Form: Participant Creation

Data signed: (b) (4) 02 Apr 2021 20:33:44

Generated On: 09 Jun 2021 15:03:08

Participant ID

US3062128

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

US3062128

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 15:28:47

Generated On: 09 Jun 2021 15:03:08

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 06 AUG 2020 |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/> |
| | Clinic <input checked="" type="radio"/> |
| Folder OID | SCRN |

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Feb 2021 15:28:46

Generated On: 09 Jun 2021 15:03:08

| | |
|---|--|
| Date of Birth (MMM yyyy) | (b) (6) 1943 |
| Age | 77 |
| Age Units | YEARS |
| Age (Derived) | 77 |
| 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) 15 Feb 2021 15:28:46

Generated On: 09 Jun 2021 15:03:08

Date of Informed Consent (*dd MMM yyyy*) 06 AUG 2020

Month and Year of Informed Consent (derived) AUG 2020

Year of Informed Consent (derived) 2020

Protocol Version

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

Was participant enrolled in the study?

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

If No, indicate reason for screen fail

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

If reason for screen fail is Other, specify _____

Was this participant screened previously?

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

If Yes, previous participant number _____

Enrollment Trigger 1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Feb 2021 15:28:46

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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) 15 Feb 2021 15:28:47

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 15 Feb 2021 15:28:47

Generated On: 09 Jun 2021 15:03:08

| | |
|---|--|
| Condition | SEASONAL ALLERGIES |
| Start date (dd MMM yyyy) | UN JAN 1975 |
| 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 1975 |
| Start Year (derived) | 1975 |
| Stop Month and Year (derived) | _____ |
| Stop Year (derived) | _____ |

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 15 Feb 2021 15:28:47

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| | |
|---|--|
| Condition | HYPERTENSION |
| Start date (dd MMM yyyy) | UN JAN 2003 |
| 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 2003 |
| Start Year (derived) | 2003 |
| Stop Month and Year (derived) | _____ |
| Stop Year (derived) | _____ |

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 15 Feb 2021 15:28:47

Generated On: 09 Jun 2021 15:03:08

| | |
|---|--|
| Condition | GASTROESOPHAGEAL REFLUX DISORDER |
| Start date (dd MMM yyyy) | UN JAN 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 (4)

Data signed: (b) (4) 15 Feb 2021 15:28:47

Generated On: 09 Jun 2021 15:03:08

| | |
|---|--|
| Condition | POST MENOPAUSAL |
| Start date (dd MMM yyyy) | UN JAN 1988 |
| 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 1988 |
| Start Year (derived) | 1988 |
| Stop Month and Year (derived) | _____ |
| Stop Year (derived) | _____ |

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 15 Feb 2021 15:28:47

Generated On: 09 Jun 2021 15:03:08

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

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 15 Feb 2021 15:28:47

Generated On: 09 Jun 2021 15:03:08

| | |
|---|--|
| Condition | INSOMNIA |
| Start date (dd MMM yyyy) | UN JAN 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 (7)

Data signed: (b) (4) 15 Feb 2021 15:28:47

Generated On: 09 Jun 2021 15:03:08

| | |
|---|--|
| Condition | OSTEOARTHRITIS, GENERALIZED |
| Start date (dd MMM yyyy) | UN JAN 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: Vital Signs

Data signed: (b) (4) 15 Feb 2021 15:28:47

Generated On: 09 Jun 2021 15:03:08

| | |
|---|--------------------------------------|
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (<i>dd MMM yyyy</i>) | 06 AUG 2020 |
| Time of assessment (<i>00:00-23:59</i>) | 15:32 (24 HR) |
| Vital Signs Date and Time (derived) | 06 AUG 2020 15:32 |
| Height (<i>xxx.x</i>) | 170.5 cm |
| Weight (<i>xxx.x</i>) | 79.1 kg |
| BMI (<i>xxx.x</i>) | 27.20995 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) 15 Feb 2021 15:28:47

Generated On: 09 Jun 2021 15:03:08

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

06 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) 15 Feb 2021 15:28:46

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Date of assessment (*dd MMM yyyy*) 6 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*) UN JAN 1988

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 15:28:47

Generated On: 09 Jun 2021 15:03:08

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) 15 Feb 2021 15:28:47

Generated On: 09 Jun 2021 15:03:08

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 15:28:48

Generated On: 09 Jun 2021 15:03:08

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 06 AUG 2020 |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/> |
| | Clinic <input checked="" type="radio"/> |
| Folder OID | VISIT1 |

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 15 Feb 2021 15:28:47

Generated On: 09 Jun 2021 15:03:08

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

What was the participant's randomization number? 185026

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 15 Feb 2021 15:28:48

Generated On: 09 Jun 2021 15:03:08

| | |
|--------|---------------|
| 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) 15 Feb 2021 15:28:48

Generated On: 09 Jun 2021 15:03:08

| | |
|-------------------------------------|--|
| 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) | 06 AUG 2020 |
| Time of assessment (00:00-23:59) | 15:29 (24 HR) |
| Vital Signs Date and Time (derived) | 06 AUG 2020 15:29 |
| Temperature (xxx.x) | 98.7 F |
| Route of measurement | Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 75 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 16 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 98 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 55 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3062128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 15:28:48

Generated On: 09 Jun 2021 15:03:08

| | |
|-------------------------------------|--|
| 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) | 06 AUG 2020 |
| Time of assessment (00:00-23:59) | 17:19 (24 HR) |
| Vital Signs Date and Time (derived) | 06 AUG 2020 17:19 |
| Temperature (xxx.x) | 97.5 F |
| Route of measurement | Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 65 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 16 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 155 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 75 mmHg |
| Diastolic Blood Pressure units | MMHG |

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 15:28:47

Generated On: 09 Jun 2021 15:03:08

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 15:28:47

Generated On: 09 Jun 2021 15:03:08

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) 06 AUG 2020

What was the treatment time? (00:00-23:59) 16:48 (24 HR)

Treatment Date and Time (derived) 06 AUG 2020 16:48

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) 15 Feb 2021 15:28:47

Generated On: 09 Jun 2021 15:03:08

| | |
|--|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (<i>dd MMM yyyy</i>) | 6 AUG 2020 |
| Collection time (<i>00:00-23:59</i>) | 15:57 (24 HR) |
| Collection date and time (derived) | 6 AUG 2020 15:57 |

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 15:28:47

Generated On: 09 Jun 2021 15:03:08

| | | | |
|-------------------------------|---------------------------|---------------------------------|------------------------------------|
| Collection date (dd MMM yyyy) | | | 6 AUG 2020 |
| Lab Test | Was the sample collected? | Collection time (00:00 - 23:59) | Collection date and time (derived) |
| Nasopharyngeal Swab 1 | Yes | 15:52 | 6 AUG 2020 15:52 |
| Nasopharyngeal Swab 2 | No | | |

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 15:28:47

Generated On: 09 Jun 2021 15:03:08

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 15:03:08

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.5 °F

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

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

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

To **PREVENT** pain or fever from occurring False

PC Time Stamp 06 AUG 2020 17:29

PC Open Date & Time 06 AUG 2020 17:08

PC Close Date & Time 06 AUG 2020 19:38

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:03:08

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 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 | 06 AUG 2020 21:13 |
| PC Open Date & Time | 06 AUG 2020 20:33 |
| PC Close Date & Time | 07 AUG 2020 11:59 |

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.3 °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

07 AUG 2020 21:19

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 AUG 2020 20:59

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3062128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:03:08

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

96.7 °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

09 AUG 2020 21:31

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3062128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 AUG 2020 20:47

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3062128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 AUG 2020 21:30

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3062128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °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

12 AUG 2020 21:10

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3062128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:03:08

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

06 AUG 2020 17:30

PC Open Date & Time

06 AUG 2020 17:08

PC Close Date & Time

06 AUG 2020 19:38

US3062128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:03:08

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

06 AUG 2020 21:14

PC Open Date & Time

06 AUG 2020 20:33

PC Close Date & Time

07 AUG 2020 11:59

US3062128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:03:08

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

07 AUG 2020 21:20

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3062128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 AUG 2020 21:00

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3062128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 AUG 2020 21:31

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3062128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

10 AUG 2020 20:47

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3062128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

11 AUG 2020 21:30

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3062128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 AUG 2020 21:10

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3062128

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:08

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 ☐

US3062128

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:08

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 06 AUG 2020 17:31 |
| PC Open Date & Time | 06 AUG 2020 17:08 |
| PC Close Date & Time | 06 AUG 2020 19:38 |

US3062128

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:08

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 ☐

US3062128

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:08

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 06 AUG 2020 21:14 |
| PC Open Date & Time | 06 AUG 2020 20:33 |
| PC Close Date & Time | 07 AUG 2020 11:59 |

US3062128

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:08

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 ☒

US3062128

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:08

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 07 AUG 2020 21:20 |
| PC Open Date & Time | 07 AUG 2020 12:00 |
| PC Close Date & Time | 08 AUG 2020 11:59 |

US3062128

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:08

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 ☒

US3062128

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:08

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 08 AUG 2020 21:01 |
| PC Open Date & Time | 08 AUG 2020 12:00 |
| PC Close Date & Time | 09 AUG 2020 11:59 |

US3062128

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:08

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 ☒

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EAB) (1725)

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US3062128

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:08

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 09 AUG 2020 21:32 |
| PC Open Date & Time | 09 AUG 2020 12:00 |
| PC Close Date & Time | 10 AUG 2020 11:59 |

US3062128

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3062128

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:08

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 10 AUG 2020 20:48 |
| PC Open Date & Time | 10 AUG 2020 12:00 |
| PC Close Date & Time | 11 AUG 2020 11:59 |

US3062128

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

57 of 2894

US3062128

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:08

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 11 AUG 2020 21:31 |
| PC Open Date & Time | 11 AUG 2020 12:00 |
| PC Close Date & Time | 12 AUG 2020 11:59 |

US3062128

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

59 of 2894

US3062128

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:08

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 12 AUG 2020 21:10 |
| PC Open Date & Time | 12 AUG 2020 12:00 |
| PC Close Date & Time | 13 AUG 2020 11:59 |

US3062128

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 15:28:46

Generated On: 09 Jun 2021 15:03:08

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 13 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3062128

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 15:28:46

Generated On: 09 Jun 2021 15:03:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062128

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 15:28:46

Generated On: 09 Jun 2021 15:03:08

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 20 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3062128

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 15:28:46

Generated On: 09 Jun 2021 15:03:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062128

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 15:28:46

Generated On: 09 Jun 2021 15:03:08

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3062128

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 15:28:46

Generated On: 09 Jun 2021 15:03:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062128

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 15:28:48

Generated On: 09 Jun 2021 15:03:08

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 3 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 |

US3062128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 15:28:48

Generated On: 09 Jun 2021 15:03:08

| | |
|-------------------------------------|---|
| 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) | 03 SEP 2020 |
| Time of assessment (00:00-23:59) | 11:14 (24 HR) |
| Vital Signs Date and Time (derived) | 03 SEP 2020 11:14 |
| Temperature (xxx.x) | 98.0 F |
| 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) | 119 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 75 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3062128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 15:28:48

Generated On: 09 Jun 2021 15:03:08

| | |
|-------------------------------------|---|
| Timepoint | Pre-Dose <input type="checkbox"/> |
| | Post-Dose <input checked="" type="checkbox"/> |
| Were vital signs assessed? | Yes <input checked="" type="checkbox"/> |
| | No <input type="checkbox"/> |
| Date of assessment (dd MMM yyyy) | 03 SEP 2020 |
| Time of assessment (00:00-23:59) | 12:56 (24 HR) |
| Vital Signs Date and Time (derived) | 03 SEP 2020 12:56 |
| Temperature (xxx.x) | 98.3 F |
| Route of measurement | Oral <input checked="" type="checkbox"/> |
| | Axillary <input type="checkbox"/> |
| | Other <input type="checkbox"/> |
| If Other, specify | |
| Pulse (xxx) | 70 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 16 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 135 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 73 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3062128

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 15:28:48

Generated On: 09 Jun 2021 15:03:08

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

03 SEP 2020

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

US3062128

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 15:28:48

Generated On: 09 Jun 2021 15:03:08

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) 3 SEP 2020

What was the treatment time? (00:00-23:59) 12:15 (24 HR)

Treatment Date and Time (derived) 3 SEP 2020 12:15

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

What was the frequency of the study treatment dosing? ONCE

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

US3062128

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 15:28:48

Generated On: 09 Jun 2021 15:03:08

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

| | |
|-------------------------------|-------------|
| Collection date (dd MMM yyyy) | 03 SEP 2020 |
|-------------------------------|-------------|

| | |
|-------------------------------|---------------|
| Collection time (00:00-23:59) | 11:37 (24 HR) |
|-------------------------------|---------------|

| | |
|------------------------------------|-------------------|
| Collection date and time (derived) | 03 SEP 2020 11:37 |
|------------------------------------|-------------------|

US3062128

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 15:28:48

Generated On: 09 Jun 2021 15:03:08

| | | | |
|-------------------------------|---------------------------|---------------------------------|------------------------------------|
| Collection date (dd MMM yyyy) | | | 03 SEP 2020 |
| Lab Test | Was the sample collected? | Collection time (00:00 - 23:59) | Collection date and time (derived) |
| Nasopharyngeal Swab 1 | Yes | 11:32 | 03 SEP 2020 11:32 |
| Nasopharyngeal Swab 2 | No | | |

US3062128

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 15:28:48

Generated On: 09 Jun 2021 15:03:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:03:08

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

03 SEP 2020 12:51

PC Open Date & Time

03 SEP 2020 12:35

PC Close Date & Time

03 SEP 2020 15:05

US3062128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:03:08

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 97.9 °F

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

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

| | |
|----------------------|-------------------|
| PC Time Stamp | 03 SEP 2020 21:26 |
| PC Open Date & Time | 03 SEP 2020 16:00 |
| PC Close Date & Time | 04 SEP 2020 11:59 |

US3062128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 SEP 2020 21:15

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3062128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 SEP 2020 20:57

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3062128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:03:08

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

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 SEP 2020 21:37

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3062128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:03:08

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

07 SEP 2020 21:15

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3062128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

DAY 6

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

95.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 SEP 2020 21:39

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3062128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 SEP 2020 21:41

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3062128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 SEP 2020 12:51

PC Open Date & Time

03 SEP 2020 12:35

PC Close Date & Time

03 SEP 2020 15:05

US3062128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:03:08

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

03 SEP 2020 21:26

PC Open Date & Time

03 SEP 2020 16:00

PC Close Date & Time

04 SEP 2020 11:59

US3062128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:03:08

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

04 SEP 2020 21:15

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3062128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:03:08

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

05 SEP 2020 20:57

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3062128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:03:08

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

06 SEP 2020 21:38

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3062128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:03:08

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

07 SEP 2020 21:16

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3062128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:03:08

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

08 SEP 2020 21:39

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3062128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:03:08

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

09 SEP 2020 21:41

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3062128

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:08

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 ☐

US3062128

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:08

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

No ☒

Yes ☐

| | |
|---------------|-------------------|
| PC Time stamp | 03 SEP 2020 12:52 |
|---------------|-------------------|

| | |
|---------------------|-------------------|
| PC Open Date & Time | 03 SEP 2020 12:35 |
|---------------------|-------------------|

| | |
|----------------------|-------------------|
| PC Close Date & Time | 03 SEP 2020 15:05 |
|----------------------|-------------------|

US3062128

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:08

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 ☐

US3062128

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:08

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 03 SEP 2020 21:27 |
| PC Open Date & Time | 03 SEP 2020 16:00 |
| PC Close Date & Time | 04 SEP 2020 11:59 |

US3062128

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:08

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 ☒

US3062128

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:08

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 04 SEP 2020 21:15 |
| PC Open Date & Time | 04 SEP 2020 12:00 |
| PC Close Date & Time | 05 SEP 2020 11:59 |

US3062128

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:08

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 ☒

US3062128

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:08

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 05 SEP 2020 20:58 |
| PC Open Date & Time | 05 SEP 2020 12:00 |
| PC Close Date & Time | 06 SEP 2020 11:59 |

US3062128

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:08

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

99 of 2894

EAB) (1725)

US3062128

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:08

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 06 SEP 2020 21:38 |
| PC Open Date & Time | 06 SEP 2020 12:00 |
| PC Close Date & Time | 07 SEP 2020 11:59 |

US3062128

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

101 of 2894

EAB) (1725)

US3062128

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:08

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 07 SEP 2020 21:16 |
| PC Open Date & Time | 07 SEP 2020 12:00 |
| PC Close Date & Time | 08 SEP 2020 11:59 |

US3062128

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:08

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 ☒

US3062128

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:08

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 08 SEP 2020 21:40 |
| PC Open Date & Time | 08 SEP 2020 12:00 |
| PC Close Date & Time | 09 SEP 2020 11:59 |

US3062128

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:08

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

105 of 2894

EAB) (1725)

US3062128

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:08

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 09 SEP 2020 21:42 |
| PC Open Date & Time | 09 SEP 2020 12:00 |
| PC Close Date & Time | 10 SEP 2020 11:59 |

US3062128

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 15:28:46

Generated On: 09 Jun 2021 15:03:08

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 13 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3062128

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 15:28:46

Generated On: 09 Jun 2021 15:03:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062128

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 15:28:46

Generated On: 09 Jun 2021 15:03:08

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 17 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3062128

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 15:28:46

Generated On: 09 Jun 2021 15:03:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062128

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 15:28:46

Generated On: 09 Jun 2021 15:03:08

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 24 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3062128

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 15:28:46

Generated On: 09 Jun 2021 15:03:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062128

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 15:28:48

Generated On: 09 Jun 2021 15:03:08

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 30 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 | VISIT3 |

US3062128

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 15:28:48

Generated On: 09 Jun 2021 15:03:08

| | |
|-------------------------------------|---------------------------------------|
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 30 SEP 2020 |
| Time of assessment (00:00-23:59) | 10:00 (24 HR) |
| Vital Signs Date and Time (derived) | 30 SEP 2020 10:00 |
| Temperature (xxx.x) | 97.7 F |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 64 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 16 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 117 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 72 mmHg |
| Diastolic Blood Pressure units | MMHG |
| Height (derived) | |
| Weight (derived) | |

US3062128

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 15:28:48

Generated On: 09 Jun 2021 15:03:08

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.

US3062128

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 15:28:48

Generated On: 09 Jun 2021 15:03:08

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

30 SEP 2020

Collection time (00:00-23:59)

10:30 (24 HR)

Collection date and time (derived)

30 SEP 2020 10:30

US3062128

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 15:28:48

Generated On: 09 Jun 2021 15:03:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 OCT 2020 08:10:20

Patient Cloud Open Date & Time

06 OCT 2020 00:01

Patient Cloud Close Date & Time

10 OCT 2020 23:59

US3062128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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

14 OCT 2020 11:54:31

Patient Cloud Open Date & Time

13 OCT 2020 00:01

Patient Cloud Close Date & Time

17 OCT 2020 23:59

US3062128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 OCT 2020 07:22:29

Patient Cloud Open Date & Time

20 OCT 2020 00:01

Patient Cloud Close Date & Time

24 OCT 2020 23:59

US3062128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

| TIMEPOINT | DAY 92 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 04 NOV 2020 09:32:51 |
| Patient Cloud Open Date & Time | 03 NOV 2020 00:01 |
| Patient Cloud Close Date & Time | 07 NOV 2020 23:59 |

US3062128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

DAY 99

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 NOV 2020 07:34:02

Patient Cloud Open Date & Time

10 NOV 2020 00:01

Patient Cloud Close Date & Time

14 NOV 2020 23:59

US3062128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

| TIMEPOINT | DAY 106 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature \geq 100.4°F/38°C) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |

US3062128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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

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

Date and time of submission

Patient Cloud Open Date & Time

17 NOV 2020 00:01

Patient Cloud Close Date & Time

21 NOV 2020 23:59

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 NOV 2020 12:24:51

Patient Cloud Open Date & Time

21 NOV 2020 00:01

Patient Cloud Close Date & Time

25 NOV 2020 23:59

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 DEC 2020 18:00:56

Patient Cloud Open Date & Time

28 NOV 2020 00:01

Patient Cloud Close Date & Time

02 DEC 2020 23:59

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 DEC 2020 12:42:11

Patient Cloud Open Date & Time

05 DEC 2020 00:01

Patient Cloud Close Date & Time

09 DEC 2020 23:59

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 DEC 2020 07:45:17

Patient Cloud Open Date & Time

12 DEC 2020 00:01

Patient Cloud Close Date & Time

16 DEC 2020 23:59

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 DEC 2020 09:17:21

Patient Cloud Open Date & Time

19 DEC 2020 00:01

Patient Cloud Close Date & Time

23 DEC 2020 23:59

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 DEC 2020 07:31:47

Patient Cloud Open Date & Time

26 DEC 2020 00:01

Patient Cloud Close Date & Time

30 DEC 2020 23:59

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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

02 JAN 2021 07:33:01

Patient Cloud Open Date & Time

02 JAN 2021 00:01

Patient Cloud Close Date & Time

06 JAN 2021 23:59

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 JAN 2021 07:33:42

Patient Cloud Open Date & Time

09 JAN 2021 00:01

Patient Cloud Close Date & Time

13 JAN 2021 23:59

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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

16 JAN 2021 06:33:12

Patient Cloud Open Date & Time

16 JAN 2021 00:01

Patient Cloud Close Date & Time

20 JAN 2021 23:59

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 JAN 2021 06:20:31

Patient Cloud Open Date & Time

23 JAN 2021 00:01

Patient Cloud Close Date & Time

27 JAN 2021 23:59

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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

31 JAN 2021 15:06:00

Patient Cloud Open Date & Time

30 JAN 2021 00:01

Patient Cloud Close Date & Time

03 FEB 2021 23:59

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 FEB 2021 07:24:23

Patient Cloud Open Date & Time

06 FEB 2021 00:01

Patient Cloud Close Date & Time

10 FEB 2021 23:59

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

| TIMEPOINT | DAY 194 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 13 FEB 2021 00:04:10 |
| Patient Cloud Open Date & Time | 13 FEB 2021 00:01 |
| Patient Cloud Close Date & Time | 17 FEB 2021 23:59 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 FEB 2021 10:21:56

Patient Cloud Open Date & Time

20 FEB 2021 00:01

Patient Cloud Close Date & Time

24 FEB 2021 23:59

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 FEB 2021 00:38:13

Patient Cloud Open Date & Time

27 FEB 2021 00:01

Patient Cloud Close Date & Time

03 MAR 2021 23:59

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 MAR 2021 07:31:15

Patient Cloud Open Date & Time

06 MAR 2021 00:01

Patient Cloud Close Date & Time

10 MAR 2021 23:59

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 MAR 2021 06:49:42

Patient Cloud Open Date & Time

13 MAR 2021 00:01

Patient Cloud Close Date & Time

17 MAR 2021 23:59

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 MAR 2021 09:32:23

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 MAR 2021 07:44:48

Patient Cloud Open Date & Time

27 MAR 2021 00:01

Patient Cloud Close Date & Time

31 MAR 2021 23:59

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 APR 2021 13:46:08

Patient Cloud Open Date & Time

03 APR 2021 00:01

Patient Cloud Close Date & Time

07 APR 2021 23:59

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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

12 APR 2021 11:43:33

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 APR 2021 00:42:10

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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

Date and time of submission

24 APR 2021 00:02:28

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

DAY 271

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 MAY 2021 07:11:56

Patient Cloud Open Date & Time

01 MAY 2021 00:01

Patient Cloud Close Date & Time

05 MAY 2021 23:59

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

| 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 <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"/> |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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

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

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

| 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"/> |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

| 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 <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"/> |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

| 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"/> |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

DAY 327

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

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

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

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

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

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

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

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

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

DAY 334

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

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

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

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

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

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

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

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

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

| 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"/> |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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

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

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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 ☐ Yes ☐

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

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUL 2021 23:59

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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°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 ☐

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

DAY 362

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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 ☐

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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 ☐

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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

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

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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

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

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

DAY 390

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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 ☐

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

DAY 404

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

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

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

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

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

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

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

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

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2021 23:59

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

| 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"/> |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

DAY 418

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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

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

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 02 OCT 2021 00:01 |
| Patient Cloud Close Date & Time | 06 OCT 2021 23:59 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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°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 ☐

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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

Date and time of submission

| | |
|--|-------------------|
| Patient Cloud Open Date & Time | 09 OCT 2021 00:01 |
|--|-------------------|

| | |
|---|-------------------|
| Patient Cloud Close Date & Time | 13 OCT 2021 23:59 |
|---|-------------------|

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

DAY 439

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

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

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

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

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

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

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

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

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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

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

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

| 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"/> |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2021 23:59

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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 ☐

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

DAY 467

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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

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

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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 ☐

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

| 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"/> |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

DAY 488

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 04 DEC 2021 00:01 |
| Patient Cloud Close Date & Time | 08 DEC 2021 23:59 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

| 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"/> |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

15 DEC 2021 23:59

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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 ☐

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 18 DEC 2021 00:01 |
| Patient Cloud Close Date & Time | 22 DEC 2021 23:59 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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 ☐

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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

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

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

DAY 516

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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 ☐

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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 ☐

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

| 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"/> |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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

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

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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 ☐

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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

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

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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 ☐

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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 ☐

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

DAY 572

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

No ☐

Yes ☐

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

No ☐

Yes ☐

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

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

☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

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

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

Chills

Cough

Shortness of breath

Difficulty breathing

Fatigue

Muscle aches

Body aches

Headache

New loss of taste

New loss of smell

Sore throat

Congestion

Runny nose

Nausea

Vomiting

Diarrhea

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

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

☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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 ☐

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

DAY 586

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAR 2022 23:59

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

| 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"/> |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAR 2022 23:59

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

| TIMEPOINT | DAY 607 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <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"/> |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

06 APR 2022 23:59

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

| 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"/> |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 APR 2022 23:59

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

| 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"/> |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

20 APR 2022 23:59

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

| TIMEPOINT | DAY 628 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

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Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 APR 2022 00:01

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27 APR 2022 23:59

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

| TIMEPOINT | DAY 635 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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°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 ☐

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

| 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="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"/> |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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 ☐

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2022 00:01

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08 JUN 2022 23:59

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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 ☐

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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

Date and time of submission

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11 JUN 2022 00:01

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15 JUN 2022 23:59

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

DAY 684

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2022 00:01

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22 JUN 2022 23:59

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

| 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"/> |

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 25 JUN 2022 00:01 |
| Patient Cloud Close Date & Time | 29 JUN 2022 23:59 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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

[Patient Cloud Open Date & Time](#)

02 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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 ☐

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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

[Patient Cloud Open Date & Time](#)

09 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

DAY 712

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

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

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

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

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

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

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

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

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
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|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 16 JUL 2022 00:01 |
| Patient Cloud Close Date & Time | 20 JUL 2022 23:59 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

DAY 719

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
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|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 23 JUL 2022 00:01 |
| Patient Cloud Close Date & Time | 27 JUL 2022 23:59 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

| 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"/> |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
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|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 30 JUL 2022 00:01 |
| Patient Cloud Close Date & Time | 03 AUG 2022 23:59 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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

Date and time of submission

| | |
|--|-------------------|
| Patient Cloud Open Date & Time | 13 AUG 2022 00:01 |
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|---|-------------------|
| Patient Cloud Close Date & Time | 17 AUG 2022 23:59 |
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US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

DAY 747

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2022 23:59

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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 ☐

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2022 23:59

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

| 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"/> |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2022 23:59

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

| 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"/> |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2022 23:59

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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 ☐

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

DAY 782

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

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

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

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

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

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

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

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

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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

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

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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 ☐

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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

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

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

| 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"/> |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 08 OCT 2022 00:01 |
| Patient Cloud Close Date & Time | 12 OCT 2022 23:59 |

US3062128

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 15:03:08

| Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other? | Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache? | Date & Time of Submission |
|---|--|---------------------------|
| No | | 27 FEB 2021 00:38:24 |

US3062128

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 31 Mar 2021 20:58:22

Generated On: 09 Jun 2021 15:03:08

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 27 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3062128

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 31 Mar 2021 20:58:22

Generated On: 09 Jun 2021 15:03:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062128

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:33:49

Generated On: 09 Jun 2021 15:03:08

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3062128

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:33:49

Generated On: 09 Jun 2021 15:03:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062128

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:33:58

Generated On: 09 Jun 2021 15:03:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

6 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3062128

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:33:58

Generated On: 09 Jun 2021 15:03:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062128

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:33:58

Generated On: 09 Jun 2021 15:03:08

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 3 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3062128

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:33:58

Generated On: 09 Jun 2021 15:03:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062128

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 20:33:58

Generated On: 09 Jun 2021 15:03:08

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

| | |
|--------------------------|-------------|
| Visit date (dd MMM yyyy) | 19 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 | VISIT4 |
|------------|--------|

US3062128

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 20:33:58

Generated On: 09 Jun 2021 15:03:08

| | |
|---|---------------------------------------|
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (<i>dd MMM yyyy</i>) | 19 FEB 2021 |
| Time of assessment (<i>00:00-23:59</i>) | 10:55 (24 HR) |
| Vital Signs Date and Time (derived) | 19 FEB 2021 10:55 |
| Temperature (<i>xxx.x</i>) | 97.7 F |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (<i>xxx</i>) | 73 beats/min |
| Pulse units | BPM |
| Respiratory Rate (<i>xxx</i>) | 12 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (<i>xxx</i>) | 130 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (<i>xxx</i>) | 72 mmHg |
| Diastolic Blood Pressure units | MMHG |
| Height (derived) | |
| Weight (derived) | |

US3062128

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 20:33:58

Generated On: 09 Jun 2021 15:03:08

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.

US3062128

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 20:33:58

Generated On: 09 Jun 2021 15:03:08

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

19 FEB 2021

Collection time (00:00-23:59)

11:04 (24 HR)

Collection date and time (derived)

19 FEB 2021 11:04

US3062128

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:33:58

Generated On: 09 Jun 2021 15:03:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062128

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:33:58

Generated On: 09 Jun 2021 15:03:08

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 31 MAR 2021

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

Comments

If Contact Not Made, please provide Comments

US3062128

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:33:58

Generated On: 09 Jun 2021 15:03:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062128

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:08

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

US3062128

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:08

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3062128

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:03:08

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

US3062128

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 15:03:08

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3062128

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

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 20:33:49

Generated On: 09 Jun 2021 15:03:08

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

| | |
|--------------------------|-------------|
| Visit date (dd MMM yyyy) | 27 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 |
|------------|---------------|

US3062128

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

Form: Unblinding

Data signed: (b) (4) 02 Apr 2021 20:33:49

Generated On: 09 Jun 2021 15:03:08

| | |
|---|---|
| Date of updated informed consent (<i>dd MMM yyyy</i>) | 27 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>) | 27 JAN 2021 |
| Participant randomization assignment | mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> |
| Actual Dose 1 | mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/> |
| Actual Dose 2 | mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/> |
| Will participant receive mRNA-1273? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Placebo Only Flag | 1 |
| Continuing with mRNA-1273 | 1 |

US3062128

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 02 Apr 2021 20:33:49

Generated On: 09 Jun 2021 15:03:08

| | |
|-------------|----------|
| Height | 170.5 cm |
| Weight | 76.5 kg |
| BMI (xxx.x) | 26.31556 |

US3062128

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 02 Apr 2021 20:33:49

Generated On: 09 Jun 2021 15:03:08

| | |
|-------------------------------------|--|
| Height | 170.5 cm |
| Weight | 76.5 kg |
| BMI (xxx.x) | 26.31556 |
| 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) | 27 JAN 2021 |
| Time of assessment (00:00-23:59) | 09:35 (24 HR) |
| Vital Signs Date and Time (derived) | 27 JAN 2021 09:35 |
| Temperature (xxx.x) | 97.4 F |
| Route of measurement | Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 75 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 16 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 107 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 60 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3062128

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 02 Apr 2021 20:33:49

Generated On: 09 Jun 2021 15:03:08

| | |
|-------------------------------------|--|
| Height | 170.5 cm |
| Weight | 76.5 kg |
| BMI (xxx.x) | 26.31556 |
| 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) | 27 JAN 2021 |
| Time of assessment (00:00-23:59) | 11:15 (24 HR) |
| Vital Signs Date and Time (derived) | 27 JAN 2021 11:15 |
| Temperature (xxx.x) | 97.6 F |
| Route of measurement | Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 71 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 16 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 137 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 73 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3062128

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

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 20:33:49

Generated On: 09 Jun 2021 15:03:08

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

27 JAN 2021

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

US3062128

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

Form: Exposure

Data signed: (b) (4) 02 Apr 2021 20:33:49

Generated On: 09 Jun 2021 15:03:08

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) 27 JAN 2021

What was the treatment time? (00:00-23:59) 10:43 (24 HR)

Treatment Date and Time (derived) 27 JAN 2021 10:43

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

US3062128

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 20:33:49

Generated On: 09 Jun 2021 15:03:08

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

27 JAN 2021

Collection time (00:00-23:59)

09:47 (24 HR)

Collection date and time (derived)

27 JAN 2021 09:47

US3062128

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 02 Apr 2021 20:33:49

Generated On: 09 Jun 2021 15:03:08

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

| | |
|-------------------------------|-------------|
| Collection date (dd MMM yyyy) | 27 JAN 2021 |
|-------------------------------|-------------|

| | |
|---------------------------------|-------|
| Collection time (00:00 - 23:59) | 09:49 |
|---------------------------------|-------|

| | |
|------------------------------------|-------------------|
| Collection Date and Time (derived) | 27 JAN 2021 09:49 |
|------------------------------------|-------------------|

US3062128

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

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:33:49

Generated On: 09 Jun 2021 15:03:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062128

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:33:58

Generated On: 09 Jun 2021 15:03:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

3 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3062128

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:33:58

Generated On: 09 Jun 2021 15:03:08

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

US3062128

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 20:33:48

Generated On: 09 Jun 2021 15:03:08

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

| | |
|--------------------------|-------------|
| Visit date (dd MMM yyyy) | 24 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 |
|------------|-------|

US3062128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 02 Apr 2021 20:33:48

Generated On: 09 Jun 2021 15:03:08

| | |
|-------------------------------------|---|
| 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 FEB 2021 |
| Time of assessment (00:00-23:59) | 12:24 (24 HR) |
| Vital Signs Date and Time (derived) | 24 FEB 2021 12:24 |
| Temperature (xxx.x) | 97.8 F |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 83 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 16 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 106 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 69 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3062128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 02 Apr 2021 20:33:48

Generated On: 09 Jun 2021 15:03:08

| | |
|-------------------------------------|---|
| Timepoint | Pre-Dose <input type="checkbox"/> |
| | Post-Dose <input checked="" type="checkbox"/> |
| Were vital signs assessed? | Yes <input checked="" type="checkbox"/> |
| | No <input type="checkbox"/> |
| Date of assessment (dd MMM yyyy) | 24 FEB 2021 |
| Time of assessment (00:00-23:59) | 13:40 (24 HR) |
| Vital Signs Date and Time (derived) | 24 FEB 2021 13:40 |
| Temperature (xxx.x) | 98.4 F |
| Route of measurement | Oral <input checked="" type="checkbox"/> |
| | Axillary <input type="checkbox"/> |
| | Other <input type="checkbox"/> |
| If Other, specify | |
| Pulse (xxx) | 80 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 14 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 111 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 71 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3062128

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 20:33:48

Generated On: 09 Jun 2021 15:03:08

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

24 FEB 2021

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

US3062128

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 02 Apr 2021 20:33:48

Generated On: 09 Jun 2021 15:03:08

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) 24 FEB 2021

What was the treatment time? (00:00-23:59) 13:09 (24 HR)

Treatment Date and Time (derived) 24 FEB 2021 13:09

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

US3062128

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:33:48

Generated On: 09 Jun 2021 15:03:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062128

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:33:58

Generated On: 09 Jun 2021 15:03:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

08 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3062128

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:33:58

Generated On: 09 Jun 2021 15:03:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062128

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 20:33:49

Generated On: 09 Jun 2021 15:03:08

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

| | |
|--------------------------|-------------|
| Visit date (dd MMM yyyy) | 24 MAR 2021 |
|--------------------------|-------------|

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

| | |
|------------|-------|
| Folder OID | OLD57 |
|------------|-------|

US3062128

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 20:33:49

Generated On: 09 Jun 2021 15:03:08

| | |
|---|---------------------------------------|
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (<i>dd MMM yyyy</i>) | 24 MAR 2021 |
| Time of assessment (<i>00:00-23:59</i>) | 10:59 (24 HR) |
| Vital Signs Date and Time (derived) | 24 MAR 2021 10:59 |
| Temperature (<i>xxx.x</i>) | 97.9 F |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (<i>xxx</i>) | 84 beats/min |
| Pulse units | BPM |
| Respiratory Rate (<i>xxx</i>) | 16 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (<i>xxx</i>) | 117 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (<i>xxx</i>) | 77 mmHg |
| Diastolic Blood Pressure units | MMHG |
| Height (derived) | |
| Weight (derived) | |

US3062128

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 20:33:49

Generated On: 09 Jun 2021 15:03:08

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.

US3062128

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 20:33:49

Generated On: 09 Jun 2021 15:03:08

| | |
|------------------------------------|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (dd MMM yyyy) | 24 MAR 2021 |
| Collection time (00:00-23:59) | 11:07 (24 HR) |
| Collection date and time (derived) | 24 MAR 2021 11:07 |

US3062128

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 31 Mar 2021 20:58:22

Generated On: 09 Jun 2021 15:03:08

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3062128

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 31 Mar 2021 20:58:21

Generated On: 09 Jun 2021 15:03:08

| | |
|--|--|
| AEID | USA-US090-2020-MRNA-1273-P30 1000010 |
| Adverse event | WORSENING OSTEOARTHRITIS RIGHT KNEE |
| 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) | 03 DEC 2020 |
| Start time (00:00-23:59) | |
| AE start date and time (derived) | |
| Ongoing? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| If not Ongoing, end date (dd MMM yyyy) | 04 DEC 2020 |
| End time (00:00-23:59) | |
| AE End Date and Time (derived) | |
| Severity | Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input 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) | 03 DEC 2020 |
| Hospital Discharge Date (dd MMM yyyy) | 04 DEC 2020 |
| Admitted to ICU? | Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/> |
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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 31 Mar 2021 20:58:21

Generated On: 09 Jun 2021 15:03:08

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

US3062128

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 31 Mar 2021 20:58:21

Generated On: 09 Jun 2021 15:03:08

SUBJECT WAS ADMITTED TO HOSPITAL FOR WORSENING OF RIGHT KNEE OSTEOARTHRITIS. SUBJECT UNDERWENT A RIGHT KNEE REPLACEMENT ON 12/3/2020. SUBJECT WAS DISCHARGED FROM THE HOSPITAL IN STABLE CONDITION ON 12/4/2020 TO HER OWN HOME. RELEASE OF RECORDS MAILED TO SUBJECT. INFORMATION FROM INITIAL SAE REMAINS UNCHANGED AND CORRECT, FOLLOW UP INFORMATION GATHERED FROM MEDICAL RECORDS RECEIVED INCLUDES ADDITIONAL AES AND CONMEDS.

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

US3062128

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 31 Mar 2021 20:58:21

Generated On: 09 Jun 2021 15:03:08

AEID

Adverse event

POSTOPERATIVE PAIN

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)

03 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

1 JAN 2021

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 (2)

Data signed: (b) (4) 31 Mar 2021 20:58:21

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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 | 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 | |
| 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 (3)

Data signed: (b) (4) 31 Mar 2021 20:58:21

Generated On: 09 Jun 2021 15:03:08

AEID

Adverse event

BLADDER INFECTION

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)

30 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

03 DEC 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 (3)

Data signed: (b) (4) 31 Mar 2021 20:58:21

Generated On: 09 Jun 2021 15:03:08

| | |
|---|---|
| Persistent or significant disability or incapacity | False |
| Congenital anomaly or birth defect | False |
| Other medically important event | False |
| Relationship to investigational product | Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/> |
| Relationship to Study Procedure | Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/> |
| Action taken with investigational product | None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/> |
| Other action taken (check all that apply) | |
| None | False |
| Concomitant Medication | True |
| Concomitant Procedure | False |
| Outcome | Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/> |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____ | |
| Narrative _____ | |
| 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 (4)

Data signed: (b) (4) 31 Mar 2021 20:58:21

Generated On: 09 Jun 2021 15:03:08

AEID

Adverse event

POST OP CONSTIPATION

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)

03 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

04 DEC 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 (4)

Data signed: (b) (4) 31 Mar 2021 20:58:21

Generated On: 09 Jun 2021 15:03:08

| | |
|--|---|
| Persistent or significant disability or incapacity | False |
| Congenital anomaly or birth defect | False |
| Other medically important event | False |
| Relationship to investigational product | Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/> |
| Relationship to Study Procedure | Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/> |
| Action taken with investigational product | None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/> |
| Other action taken (check all that apply) | |
| None | False |
| Concomitant Medication | True |
| Concomitant Procedure | False |
| Outcome | Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/> |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: | |
| Narrative | |
| 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 (5)

Data signed: (b) (4) 31 Mar 2021 20:58:21

Generated On: 09 Jun 2021 15:03:08

AEID

Adverse event

NAUSEA, RECURRENT

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)

03 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

04 DEC 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 (5)

Data signed: (b) (4) 31 Mar 2021 20:58:21

Generated On: 09 Jun 2021 15:03:08

| | |
|--|---|
| Persistent or significant disability or incapacity | False |
| Congenital anomaly or birth defect | False |
| Other medically important event | False |
| Relationship to investigational product | Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/> |
| Relationship to Study Procedure | Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/> |
| Action taken with investigational product | None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/> |
| Other action taken (check all that apply) | |
| None | False |
| Concomitant Medication | True |
| Concomitant Procedure | False |
| Outcome | Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/> |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: | |
| Narrative | |
| 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 (6)

Data signed: (b) (4) 31 Mar 2021 20:58:21

Generated On: 09 Jun 2021 15:03:08

| | |
|--|--|
| AEID | |
| Adverse event | ANEMIA |
| Was this a medically-attended AE? | Yes <input type="radio"/> No <input checked="" 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) | 04 DEC 2020 |
| Start time (00:00-23:59) | |
| AE start date and time (derived) | |
| Ongoing? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| If not Ongoing, end date (dd MMM yyyy) | |
| End time (00:00-23:59) | |
| AE End Date and Time (derived) | |
| Severity | Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/> |
| Is the adverse event serious? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| AE is serious due To (check all that apply) | |
| Death | False |
| Life threatening | False |
| Requires inpatient or prolongation of existing Hospitalization | False |
| Hospital Admission Date (dd MMM yyyy) | |
| Hospital Discharge Date (dd MMM yyyy) | |
| Admitted to ICU? | Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/> |
| Number of Days in ICU | |

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 31 Mar 2021 20:58:21

Generated On: 09 Jun 2021 15:03:08

| | |
|--|---|
| 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 checked="" type="radio"/> Recovered/Resolved <input 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) | |

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 31 Mar 2021 20:58:21

Generated On: 09 Jun 2021 15:03:08

| | |
|--|--|
| AEID | |
| Adverse event | RESTLESS LEG SYNDROME |
| Was this a medically-attended AE? | Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> |
| Was this a Solicited Adverse Reaction? | Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> |
| Is this event a confirmed diagnosis of Symptomatic Covid-19? | Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> |
| Start date (dd MMM yyyy) | 02 NOV 2020 |
| Start time (00:00-23:59) | |
| AE start date and time (derived) | |
| Ongoing? | Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> |
| If not Ongoing, end date (dd MMM yyyy) | |
| End time (00:00-23:59) | |
| AE End Date and Time (derived) | |
| Severity | Grade 1/Mild <input checked="" type="checkbox"/> Grade 2/Moderate <input type="checkbox"/> Grade 3/Severe <input type="checkbox"/> Grade 4 <input type="checkbox"/> |
| Is the adverse event serious? | Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> |
| AE is serious due To (check all that apply) | |
| Death | False |
| Life threatening | False |
| Requires inpatient or prolongation of existing Hospitalization | False |
| Hospital Admission Date (dd MMM yyyy) | |
| Hospital Discharge Date (dd MMM yyyy) | |
| Admitted to ICU? | Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/> |
| Number of Days in ICU | |

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Folder: Adverse Events

Form: Adverse Events (7)

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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 checked="" type="radio"/> Recovered/Resolved <input 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) | |

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 31 Mar 2021 20:58:21

Generated On: 09 Jun 2021 15:03:08

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

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 31 Mar 2021 20:58:21

Generated On: 09 Jun 2021 15:03:08

| | |
|--|---|
| 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 checked="" type="radio"/> Recovered/Resolved <input 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) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 02 Apr 2021 20:33:48

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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) 02 Apr 2021 20:33:45

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Name of Medication BONIVA

Prophylaxis Yes ☐
No ☒

Indication OSTEOGENON

Dose per administration 150

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 02 Apr 2021 20:33:45

Generated On: 09 Jun 2021 15:03:08

| | | |
|--|--------------------------|----------------------------------|
| | 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 JAN 2010 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | 1 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input checked="" 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 (2)

Data signed: (b) (4) 02 Apr 2021 20:33:45

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Name of Medication HYDROCHLOROTHIAZIDE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 12

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) 02 Apr 2021 20:33:45

Generated On: 09 Jun 2021 15:03:08

| | | |
|--|--------------------------|----------------------------------|
| | 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 JAN 2003 | |
| 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 (3)

Data signed: (b) (4) 02 Apr 2021 20:33:45

Generated On: 09 Jun 2021 15:03:08

Name of Medication POTASSIUM

Prophylaxis Yes ☒
No ☐

Indication NUTRITIONAL SUPPLEMENT

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 02 Apr 2021 20:33:45

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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 JUN 2014 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | 1 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 02 Apr 2021 20:33:45

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Name of Medication RANITIDINE

Prophylaxis Yes ☐
No ☒

Indication GASTROESOPHAGEAL REFLUX
DISORDER

Dose per administration 150

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 02 Apr 2021 20:33:45

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| | | |
|--|--------------------------|----------------------------------|
| | Intraocular | <input type="radio"/> |
| | Intramuscular | <input type="radio"/> |
| | Respiratory (Inhalation) | <input type="radio"/> |
| | Intralesional | <input type="radio"/> |
| | Intraperitoneal | <input type="radio"/> |
| | Nasal | <input type="radio"/> |
| | Vaginal | <input type="radio"/> |
| | Rectal | <input type="radio"/> |
| | Intravenous | <input type="radio"/> |
| | Intravenous Bolus | <input type="radio"/> |
| | Intravenous Drip | <input type="radio"/> |
| | Other | <input type="radio"/> |
| If route of administration is Other, specify | | |
| Start date (dd MMM yyyy) | UN JAN 2010 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | 1 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 02 Apr 2021 20:33:45

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Name of Medication ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication CARDIAC PROPHYLAXIS

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 02 Apr 2021 20:33:45

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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 JAN 1988 | |
| 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 (6)

Data signed: (b) (4) 02 Apr 2021 20:33:45

Generated On: 09 Jun 2021 15:03:08

Name of Medication CALCIUM 1200 MG /VITAMIN D
1000 IU

Prophylaxis Yes ☒
No ☐

Indication NUTRITIONAL SUPPLEMENT

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 (6)

Data signed: (b) (4) 02 Apr 2021 20:33:45

Generated On: 09 Jun 2021 15:03:08

| | | |
|--|--------------------------|----------------------------------|
| | 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) | UN JAN 1988 | |
| 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 (7)

Data signed: (b) (4) 02 Apr 2021 20:33:45

Generated On: 09 Jun 2021 15:03:08

Name of Medication MAGNESIUM

Prophylaxis Yes ☒
No ☐

Indication NUTRITIONAL SUPPLEMENT

Dose per administration 400

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 (7)

Data signed: (b) (4) 02 Apr 2021 20:33:45

Generated On: 09 Jun 2021 15:03:08

| | | |
|--|--------------------------|----------------------------------|
| | 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 JAN 1988 | |
| 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 (8)

Data signed: (b) (4) 02 Apr 2021 20:33:45

Generated On: 09 Jun 2021 15:03:08

Name of Medication L-LYSINE

Prophylaxis Yes ☒
No ☐

Indication NUTRITIONAL SUPPLEMENT

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 (8)

Data signed: (b) (4) 02 Apr 2021 20:33:45

Generated On: 09 Jun 2021 15:03:08

| | | |
|--|--------------------------|----------------------------------|
| | 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 JAN 1988 | |
| 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 (9)

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Name of Medication LUTEIN

Prophylaxis Yes ☒
No ☐

Indication NUTRITIONAL SUPPLEMENT

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 02 Apr 2021 20:33:45

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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 JAN 1988 | |
| 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 (10)

Data signed: (b) (4) 02 Apr 2021 20:33:45

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Name of Medication FISH OIL

Prophylaxis Yes ☒
No ☐

Indication NUTRITIONAL SUPPLEMENT

Dose per administration 1400

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 (10)

Data signed: (b) (4) 02 Apr 2021 20:33:45

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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 JAN 1988 | |
| 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 (11)

Data signed: (b) (4) 02 Apr 2021 20:33:45

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Name of Medication DIPHENHYDRAMINE

Prophylaxis Yes ☐
No ☒

Indication INSOMNIA

Dose per administration 30

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 (11)

Data signed: (b) (4) 02 Apr 2021 20:33:45

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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 JUN 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 type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 02 Apr 2021 20:33:45

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Name of Medication CLARITIN

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

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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 JAN 2005 | |
| 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 (13)

Data signed: (b) (4) 02 Apr 2021 20:33:45

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Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication OSTEOARTHRITIS,
GENERALIZED

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 (13)

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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) | UN JAN 2015 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | | |
| 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 (14)

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Name of Medication MELOXICAM

Prophylaxis Yes ☐
No ☒

Indication OSTEOARTHRITIS,
GENERALIZED

Dose per administration 15

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

If dose unit is Other, specify

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

If frequency is Other, specify

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) 02 Apr 2021 20:33:45

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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) | 12 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) | 01 SEP 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 (15)

Data signed: (b) (4) 02 Apr 2021 20:33:45

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Name of Medication MELOXICAM

Prophylaxis Yes ☐
No ☒

Indication OSTEOARTHRITIS-GENERALIZED

Dose per administration 7.5

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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

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| | | |
|--|--------------------------|----------------------------------|
| | Intraocular | <input type="radio"/> |
| | Intramuscular | <input type="radio"/> |
| | Respiratory (Inhalation) | <input type="radio"/> |
| | Intralesional | <input type="radio"/> |
| | Intraperitoneal | <input type="radio"/> |
| | Nasal | <input type="radio"/> |
| | Vaginal | <input type="radio"/> |
| | Rectal | <input type="radio"/> |
| | Intravenous | <input type="radio"/> |
| | Intravenous Bolus | <input type="radio"/> |
| | Intravenous Drip | <input type="radio"/> |
| | Other | <input type="radio"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | | 02 SEP 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) 02 Apr 2021 20:33:45

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Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication INFLUENZA PROPHALYXIS

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

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| | | |
|--|--------------------------|----------------------------------|
| | Intramuscular | <input checked="" type="radio"/> |
| | Respiratory (Inhalation) | <input type="radio"/> |
| | Intralesional | <input type="radio"/> |
| | Intraperitoneal | <input type="radio"/> |
| | Nasal | <input type="radio"/> |
| | Vaginal | <input type="radio"/> |
| | Rectal | <input type="radio"/> |
| | Intravenous | <input type="radio"/> |
| | Intravenous Bolus | <input type="radio"/> |
| | Intravenous Drip | <input type="radio"/> |
| | Other | <input type="radio"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | | 19 SEP 2020 |
| Start date completely unknown | | False |
| Ongoing? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) 19 SEP 2020 | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) _____ | | |
| Interval Dosage Unit Number (derived) _____ | | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 02 Apr 2021 20:33:45

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Name of Medication BACTRIM DS (80/160MG)

Prophylaxis Yes ☐
No ☒

Indication BLADDER INFECTION

Dose per administration 1

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 (17)

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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) | 30 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) | | 03 DEC 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 (18)

Data signed: (b) (4) 02 Apr 2021 20:33:45

Generated On: 09 Jun 2021 15:03:08

Name of Medication AMITRIPTYLENE

Prophylaxis Yes ☐
No ☒

Indication INSOMNIA

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 ☐
Intraocular ☐

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Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 02 Apr 2021 20:33:45

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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) | | 30 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) | | 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 (19)

Data signed: (b) (4) 02 Apr 2021 20:33:45

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Name of Medication TRAMADOL

Prophylaxis Yes ☐
No ☒

Indication POSTOPERATIVE PAIN

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 ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 02 Apr 2021 20:33:45

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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) | | 03 DEC 2020 |
| Start date completely unknown | | False |
| Ongoing? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) 1 JAN 2021 | | |
| Was this medication taken for solicited event? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived) _____ | | |
| Interval Dosage Unit Number (derived) _____ | | |
| Interval Dosage Definition (derived) | 802 | <input type="checkbox"/> |
| | 803 | <input type="checkbox"/> |
| | 804 | <input type="checkbox"/> |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 02 Apr 2021 20:33:45

Generated On: 09 Jun 2021 15:03:08

Name of Medication HYDROCHLOROTHIAZIDE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENTION

Dose per administration 12.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 02 Apr 2021 20:33:45

Generated On: 09 Jun 2021 15:03:08

| | | |
|--|--------------------------|----------------------------------|
| | 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 DEC 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 (21)

Data signed: (b) (4) 02 Apr 2021 20:33:45

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Name of Medication K-DUR

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 10

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

If dose unit is Other, specify MEQ

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 (21)

Data signed: (b) (4) 02 Apr 2021 20:33:45

Generated On: 09 Jun 2021 15:03:08

| | | |
|--|--------------------------|----------------------------------|
| | 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 DEC 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 (22)

Data signed: (b) (4) 02 Apr 2021 20:33:45

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Name of Medication NORMAL SALINE

Prophylaxis Yes ☐
No ☒

Indication WORSENING OSTEOARTHRITIS
RIGHT KNEE

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

EVERY HOUR

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 02 Apr 2021 20:33:45

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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) | 3 DEC 2020 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) | | 4 DEC 2020 |
| Was this medication taken for solicited event? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived) | | |
| Interval Dosage Unit Number (derived) | | |
| Interval Dosage Definition (derived) | 802 | <input type="checkbox"/> |
| | 803 | <input type="checkbox"/> |
| | 804 | <input type="checkbox"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 02 Apr 2021 20:33:45

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Name of Medication KEFZOL

Prophylaxis Yes ☐
No ☒

Indication WORSENING OSTEOARTHRITIS
RIGHT KNEE

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 (23)

Data signed: (b) (4) 02 Apr 2021 20:33:45

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 02 Apr 2021 20:33:45

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Name of Medication VANCOMYCIN

Prophylaxis Yes ☐
No ☒

Indication WORSENING OSTEOARTHRITIS
RIGHT KNEE

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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 02 Apr 2021 20:33:45

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 02 Apr 2021 20:33:45

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Name of Medication LACTATED RINGERS

Prophylaxis Yes ☐
No ☒

Indication WORSENING OSTEOARTHRITIS
RIGHT KNEE

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

EVERY HOUR

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 02 Apr 2021 20:33:45

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 02 Apr 2021 20:33:45

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Name of Medication DECADRON

Prophylaxis Yes ☐
No ☒

Indication NAUSEA-RECURRENT

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 02 Apr 2021 20:33:45

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Name of Medication REGLAN

Prophylaxis Yes ☐
No ☒

Indication NAUSEA- RECURRENT

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 02 Apr 2021 20:33:45

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Name of Medication ZOFRAN

Prophylaxis Yes ☐
No ☒

Indication NAUSEA-RECURRENT

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 (28)

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 02 Apr 2021 20:33:45

Generated On: 09 Jun 2021 15:03:08

Name of Medication PEPCID

Prophylaxis Yes ☐
No ☒

Indication NAUSEA-RECURRENT

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 02 Apr 2021 20:33:45

Generated On: 09 Jun 2021 15:03:08

| | | |
|--|-------------------------------------|----------------------------------|
| | Intramuscular | <input type="radio"/> |
| | Respiratory (Inhalation) | <input type="radio"/> |
| | Intralesional | <input type="radio"/> |
| | Intraperitoneal | <input type="radio"/> |
| | Nasal | <input type="radio"/> |
| | Vaginal | <input type="radio"/> |
| | Rectal | <input type="radio"/> |
| | Intravenous | <input checked="" type="radio"/> |
| | Intravenous Bolus | <input type="radio"/> |
| | Intravenous Drip | <input type="radio"/> |
| | Other | <input type="radio"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | 3 DEC 2020 | |
| Start date completely unknown | False | |
| Ongoing? | Yes <input type="radio"/> | |
| | No <input checked="" type="radio"/> | |
| If not Ongoing, End date (dd MMM yyyy) 3 DEC 2020 | | |
| Was this medication taken for solicited event? | Yes <input type="radio"/> | |
| | No <input checked="" type="radio"/> | |
| Separate Dosage Number (derived) _____ | | |
| Interval Dosage Unit Number (derived) _____ | | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 02 Apr 2021 20:33:45

Generated On: 09 Jun 2021 15:03:08

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication POST OPERATIVE PAIN

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 ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 02 Apr 2021 20:33:45

Generated On: 09 Jun 2021 15:03:08

| | | |
|--|--------------------------|-------------------------------------|
| | 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) | | 3 DEC 2020 |
| Start date completely unknown | | False |
| Ongoing? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) | | 01 JAN 2021 |
| 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 (32)

Data signed: (b) (4) 02 Apr 2021 20:33:45

Generated On: 09 Jun 2021 15:03:08

Name of Medication MAGNESIUM OXIDE

Prophylaxis Yes ☐
No ☒

Indication POST OPERATIVE
CONSTIPATION

Dose per administration 400

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 (32)

Data signed: (b) (4) 02 Apr 2021 20:33:45

Generated On: 09 Jun 2021 15:03:08

| | | |
|--|--------------------------|-------------------------------------|
| | 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 DEC 2020 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) | | 4 DEC 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 (33)

Data signed: (b) (4) 02 Apr 2021 20:33:45

Generated On: 09 Jun 2021 15:03:08

Name of Medication MIRALAX

Prophylaxis Yes ☐
No ☒

Indication POST OPERATIVE
CONSTIPATION

Dose per administration 17

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 (33)

Data signed: (b) (4) 02 Apr 2021 20:33:45

Generated On: 09 Jun 2021 15:03:08

| | | |
|--|--------------------------|-------------------------------------|
| | 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 DEC 2020 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) | 4 DEC 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 (34)

Data signed: (b) (4) 02 Apr 2021 20:33:45

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Name of Medication SENNA

Prophylaxis Yes ☐
No ☒

Indication POST OPERATIVE
CONSTIPATION

Dose per administration 17.2

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 (34)

Data signed: (b) (4) 02 Apr 2021 20:33:45

Generated On: 09 Jun 2021 15:03:08

| | | |
|--|--------------------------|-------------------------------------|
| | 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) | 3 DEC 2020 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) | 4 DEC 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 (35)

Data signed: (b) (4) 02 Apr 2021 20:33:45

Generated On: 09 Jun 2021 15:03:08

Name of Medication COLACE

Prophylaxis Yes ☐
No ☒

Indication POST OPERATIVE
CONSTIPATION

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
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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Data signed: (b) (4) 02 Apr 2021 20:33:45

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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) | 3 DEC 2020 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) | 4 DEC 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 (36)

Data signed: (b) (4) 02 Apr 2021 20:33:45

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Name of Medication ECOTRIN(ASPIRIN)

Prophylaxis Yes ☐
No ☒

Indication WORSENING OSTEOARTHRITIS
RIGHT KNEE

Dose per administration 81

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 (36)

Data signed: (b) (4) 02 Apr 2021 20:33:45

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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 DEC 2020 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) | | 4 DEC 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 (37)

Data signed: (b) (4) 02 Apr 2021 20:33:45

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Name of Medication NOZIN NASAL SWAB

Prophylaxis Yes ☒
No ☐

Indication INFECTION PROPHYLAXIS

Dose per administration 1

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

If dose unit is Other, specify SWAB

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 (37)

Data signed: (b) (4) 02 Apr 2021 20:33:45

Generated On: 09 Jun 2021 15:03:08

| | | |
|--|--------------------------------------|----------------------------------|
| | Intramuscular | <input type="radio"/> |
| | Respiratory (Inhalation) | <input type="radio"/> |
| | Intralesional | <input type="radio"/> |
| | Intraperitoneal | <input type="radio"/> |
| | Nasal | <input checked="" type="radio"/> |
| | Vaginal | <input type="radio"/> |
| | Rectal | <input type="radio"/> |
| | Intravenous | <input type="radio"/> |
| | Intravenous Bolus | <input type="radio"/> |
| | Intravenous Drip | <input type="radio"/> |
| | Other | <input type="radio"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | 3 DEC 2020 | |
| Start date completely unknown | False | |
| Ongoing? | Yes <input type="radio"/> | |
| | No <input checked="" type="radio"/> | |
| If not Ongoing, End date (dd MMM yyyy) 3 DEC 2020 | | |
| Was this medication taken for solicited event? | Yes <input type="radio"/> | |
| | No <input checked="" type="radio"/> | |
| Separate Dosage Number (derived) | 2 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 <input type="radio"/> | |
| | 803 <input type="radio"/> | |
| | 804 <input checked="" type="radio"/> | |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Data signed: (b) (4) 02 Apr 2021 20:33:45

Generated On: 09 Jun 2021 15:03:08

Name of Medication AMITRIPTYLINE

Prophylaxis Yes ☐
No ☒

Indication INTERSTITIAL CYSTITIS

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

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Data signed: (b) (4) 02 Apr 2021 20:33:45

Generated On: 09 Jun 2021 15:03:08

| | | |
|--|--------------------------|----------------------------------|
| | 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 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) | 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 Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 02 Apr 2021 20:33:48

Generated On: 09 Jun 2021 15:03:08

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 02 Apr 2021 20:33:48

Generated On: 09 Jun 2021 15:03:08

| Procedure/Surgery date (dd MMM yyyy) | Procedure/Surgery | Indication | If indication is Other, specify |
|---|------------------------|---------------|---------------------------------|
| 03 DEC 2020 | RIGHT KNEE REPLACEMENT | Adverse Event | |

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 15:03:08

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

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

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:03:08

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 ☐

US3062128

Folder: SAE USA-US090-2020-MRNA-1273-P301000010

Form: Safety Report Form

Data signed: (b) (4) 02 Apr 2021 20:33:49

Generated On: 09 Jun 2021 15:03:08

| | |
|--|--|
| SAEID | USA-US090-2020-MRNA-1273-P301000010 |
| 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 | RICHARD |
| Investigator's Last Name | GLOVER |
| Site Address: Street | 700 MEDICAL CENTER DR. |
| Site Address: City | NEWTON |
| Site Address: State | KS |
| Site Address: Postal Code | 67114 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 2 |

US3062128

Folder: SAE USA-US090-2020-MRNA-1273-P301000010

Form: Safety Report Form (1)

Data signed: (b) (4) 02 Apr 2021 20:33:49

Generated On: 09 Jun 2021 15:03:08

| | |
|---|--|
| SAEID | USA-US090-2020-MRNA-1273-P301000010 |
| 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 | RICHARD |
| Investigator's Last Name | GLOVER |
| Site Address: Street | 700 MEDICAL CENTER DR. |
| Site Address: City | NEWTON |
| Site Address: State | KS |
| Site Address: Postal Code | 67114 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 2 |
| Date of submission (Pre-filled from custom function) | 10/DEC/2020 21:12 |
| 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 |

US3062128

Folder: SAE USA-US090-2020-MRNA-1273-P301000010

Form: Safety Report Form (2)

Data signed: (b) (4) 02 Apr 2021 20:33:49

Generated On: 09 Jun 2021 15:03:08

| | |
|---|--|
| SAEID | USA-US090-2020-MRNA-1273-P301000010 |
| 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 | RICHARD |
| Investigator's Last Name | GLOVER |
| Site Address: Street | 700 MEDICAL CENTER DR. |
| Site Address: City | NEWTON |
| Site Address: State | KS |
| Site Address: Postal Code | 67114 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 2 |
| Date of submission (Pre-filled from custom function) | 23/DEC/2020 10:18 |
| 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

US3062128 (Prod: Alliance for Multispecialty Research, LLC)

US3062128

Form: Participant Creation

Generated On: 09 Jun 2021 15:03:08

[Participant ID](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 30 Mar 2021 19:57:13 |
| | | |
| User entered 'US3062128' | RWS_ENDPOINT ENDPOINT (b) (4) | 06 Aug 2020 20:44:23 |
| | | |

US3062128

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:03:08

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Sep 2020 02:23:29 |
| User entered 'Yes (Y)' | Riley King (b) (4) (b) (4) | 06 Aug 2020 21:59:37 |

US3062128

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Sep 2020 02:23:29 |
| User entered '06 AUG 2020' | RWS_ENDPOINT ENDPOINT (b) (4) | 06 Aug 2020 20:44:24 |

US3062128

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|--------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Sep 2020 02:23:29 |
| User entered 'Clinic (Clinic)' | Riley King (b) (4) | 06 Aug 2020 21:59:37 |

US3062128

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:03:08

[Folder OID](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User entered 'SCRN' | System | 06 Aug 2020 21:59:37 |

US3062128

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:03:08

Date of Birth (MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Sep 2020 02:23:41 |
| User entered (b) (6) 1943' | RWS_ENDPOINT ENDPOINT (b) (4) | 06 Aug 2020 20:44:25 |

US3062128

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:03:08

[Age](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Sep 2020 02:23:41 |
| User entered '77' | Janna Martinez (b) (4) (b) (4) | 07 Aug 2020 22:47:50 |

US3062128

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:03:08

[Age Units](#)

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User entered 'YEARS' | System | 07 Aug 2020 22:47:50 |

US3062128

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:03:08

[Age \(Derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User entered '77' | System | 06 Aug 2020 21:59:12 |

US3062128

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:03:08

[Sex](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Sep 2020 02:23:41 |
| User entered 'Female (F)' | Janna Martinez (b) (4) | 07 Aug 2020 22:47:50 |
| | (b) (4) | |

US3062128

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:03:08

[Ethnicity](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Sep 2020 02:23:41 |
| User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)' | Janna Martinez (b) (4) (b) (4) | 07 Aug 2020 22:47:50 |

US3062128

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:03:08

White

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Sep 2020 02:23:41 |
| User entered 'I' | Janna Martinez (b) (4) | 07 Aug 2020 22:47:50 |
| | (b) (4) | |

US3062128

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:03:08

[Black](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Sep 2020 02:23:41 |
| User entered '0' | Janna Martinez (b) (4) (b) (4) | 07 Aug 2020 22:47:50 |

US3062128

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:03:08

[Asian](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Sep 2020 02:23:41 |
| User entered '0' | Janna Martinez (b) (4) | 07 Aug 2020 22:47:50 |
| | (b) (4) | |

US3062128

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:03:08

[American Indian or Alaska Native](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Sep 2020 02:23:41 |
| User entered '0' | Janna Martinez (b) (4) (b) (4) | 07 Aug 2020 22:47:50 |

US3062128

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:03:08

[Native Hawaiian or other Pacific Islander](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Sep 2020 02:23:41 |
| User entered '0' | Janna Martinez (b) (4) (b) (4) | 07 Aug 2020 22:47:50 |

US3062128

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:03:08

[Other](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Sep 2020 02:23:41 |
| User entered '0' | Janna Martinez (b) (4) (b) (4) | 07 Aug 2020 22:47:50 |

US3062128

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:03:08

If race is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Sep 2020 02:23:41 |
| User entered empty. | Janna Martinez (b) (4) | 07 Aug 2020 22:47:50 |
| | (b) (4) | |

US3062128

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:03:08

[Unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Sep 2020 02:23:41 |
| User entered '0' | Janna Martinez (b) (4) (b) (4) | 07 Aug 2020 22:47:50 |

US3062128

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:03:08

[Not reported](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Sep 2020 02:23:41 |
| User entered '0' | Janna Martinez (b) (4) (b) (4) | 07 Aug 2020 22:47:50 |

US3062128

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:03:08

Date of Informed Consent (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Sep 2020 02:24:04 |
| User entered '06 Aug 2020' | Riley King (b) (4) (b) (4) | 06 Aug 2020 21:59:12 |

US3062128

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User entered 'Aug 2020' | System | 06 Aug 2020 21:59:12 |

US3062128

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User entered '2020' | System | 06 Aug 2020 21:59:12 |

US3062128

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:03:08

[Protocol Version](#)

| Audit | User | Time (GMT) |
|--------------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Sep 2020 02:24:04 |
| User entered 'Amendment 1 (1)' | Riley King (b) (4) (b) (4) | 06 Aug 2020 21:59:12 |

US3062128

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Sep 2020 02:24:04 |
| User entered 'Yes (Y)' | Riley King (b) (4) (b) (4) | 06 Aug 2020 21:59:12 |

US3062128

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Sep 2020 02:24:04 |
| User entered empty. | Riley King (b) (4) | 06 Aug 2020 21:59:12 |

US3062128

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:03:08

If reason for screen fail is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Sep 2020 02:24:04 |
| User entered empty. | Riley King (b) (4) (b) (4) | 06 Aug 2020 21:59:12 |

US3062128

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:03:08

[Was this participant screened previously?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Sep 2020 02:24:04 |
| User entered 'No (N)' | Riley King (b) (4) | 06 Aug 2020 21:59:12 |

US3062128

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:03:08

[If Yes, previous participant number](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Sep 2020 02:24:04 |
| User entered empty. | RWS_ENDPOINT ENDPOINT (b) (4) | 06 Aug 2020 20:44:24 |

US3062128

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:03:08

[Enrollment Trigger](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User entered 'I' | System | 06 Aug 2020 21:59:42 |

US3062128

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Sep 2020 02:24:10 |
| User entered 'Yes (Y)' | Riley King (b) (4) | 06 Aug 2020 21:59:42 |

US3062128

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:03:08

[Were any significant conditions reported?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 14:31:08 |
| User entered 'Yes (Y)' | Janna Martinez (b) (4) (b) (4) | 07 Aug 2020 22:48:03 |

US3062128

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:03:08

[Condition](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:31:56 |
| User coded data point as SOC: Immune system disorders, HLG: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\23.0. | Coder Import (b) (4) | 07 Aug 2020 22:49:16 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0. | Coder Import (b) (4) | 07 Aug 2020 22:49:16 |
| Data point term sent to Coder | System | 07 Aug 2020 22:48:38 |
| User entered 'SEASONAL ALLERGIES' | Janna Martinez (b) (4) | 07 Aug 2020 22:48:33 |
| | (b) (4) | |

US3062128

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 14:31:56 |
| User entered 'UN Jan 1975' | Janna Martinez (b) (4) (b) (4) | 07 Aug 2020 22:48:33 |

US3062128

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:03:08

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 14:31:56 |
| User entered '0' | Janna Martinez (b) (4) (b) (4) | 07 Aug 2020 22:48:33 |

US3062128

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:03:08

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 14:31:56 |
| User entered 'Yes (Y)' | Janna Martinez (b) (4) | 07 Aug 2020 22:48:33 |
| | (b) (4) | |

US3062128

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 14:31:56 |
| User entered empty. | Janna Martinez (b) (4) (b) (4) | 07 Aug 2020 22:48:33 |

US3062128

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:03:08

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 14:31:56 |
| User entered '0' | Janna Martinez (b) (4) (b) (4) | 07 Aug 2020 22:48:33 |

US3062128

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User entered 'Jan 1975' | System | 07 Aug 2020 22:48:33 |

US3062128

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User entered '1975' | System | 07 Aug 2020 22:48:33 |

US3062128

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User entered empty. | System | 07 Aug 2020 22:48:33 |

US3062128

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User entered empty. | System | 07 Aug 2020 22:48:33 |

US3062128

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:03:08

Condition

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 14:31:56 |
| User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 07 Aug 2020 22:50:17 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 07 Aug 2020 22:50:17 |
| Data point term sent to Coder | System | 07 Aug 2020 22:49:41 |
| User entered 'HYPERTENSION' | Janna Martinez (b) (4) (b) (4) | 07 Aug 2020 22:49:06 |

US3062128

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:31:56 |
| User entered 'UN Jan 2003' | Janna Martinez (b) (4) | 07 Aug 2020 22:49:06 |
| | (b) (4) | |

US3062128

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:03:08

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 14:31:56 |
| User entered '0' | Janna Martinez (b) (4) (b) (4) | 07 Aug 2020 22:49:06 |

US3062128

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:03:08

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 14:31:56 |
| User entered 'Yes (Y)' | Janna Martinez (b) (4) | 07 Aug 2020 22:49:06 |
| | (b) (4) | |

US3062128

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 14:31:56 |
| User entered empty. | Janna Martinez (b) (4) (b) (4) | 07 Aug 2020 22:49:06 |

US3062128

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:03:08

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 14:31:56 |
| User entered '0' | Janna Martinez (b) (4) (b) (4) | 07 Aug 2020 22:49:06 |

US3062128

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User entered 'Jan 2003' | System | 07 Aug 2020 22:49:06 |

US3062128

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User entered '2003' | System | 07 Aug 2020 22:49:06 |

US3062128

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User entered empty. | System | 07 Aug 2020 22:49:06 |

US3062128

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User entered empty. | System | 07 Aug 2020 22:49:06 |

US3062128

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:03:08

Condition

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:31:56 |
| User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\\23.0. | Coder Import (b) (4) | 07 Aug 2020 22:52:19 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 07 Aug 2020 22:52:19 |
| Data point term sent to Coder | System | 07 Aug 2020 22:50:43 |
| User entered 'GASTROESOPHAGEAL REFLUX DISORDER' | Janna Martinez (b) (4) | 07 Aug 2020 22:49:58 |
| | (b) (4) | |

US3062128

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:31:56 |
| User entered 'UN Jan 2010' | Janna Martinez (b) (4) | 07 Aug 2020 22:49:58 |
| | (b) (4) | |

US3062128

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:03:08

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:31:56 |
| User entered '0' | Janna Martinez (b) (4) | 07 Aug 2020 22:49:58 |
| | (b) (4) | |

US3062128

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:03:08

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:31:56 |
| User entered 'Yes (Y)' | Janna Martinez (b) (4) | 07 Aug 2020 22:49:58 |
| | (b) (4) | |

US3062128

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:31:56 |
| User entered empty. | Janna Martinez (b) (4) | 07 Aug 2020 22:49:58 |
| | (b) (4) | |

US3062128

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:03:08

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:31:56 |
| User entered '0' | Janna Martinez (b) (4) | 07 Aug 2020 22:49:58 |
| | (b) (4) | |

US3062128

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User entered 'Jan 2010' | System | 07 Aug 2020 22:49:58 |

US3062128

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User entered '2010' | System | 07 Aug 2020 22:49:58 |

US3062128

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User entered empty. | System | 07 Aug 2020 22:49:58 |

US3062128

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User entered empty. | System | 07 Aug 2020 22:49:58 |

US3062128

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:03:08

[Condition](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:31:56 |
| User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0. | Coder Import (b) (4) | 07 Aug 2020 22:52:19 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | (b) (4) | |
| Data point term sent to Coder | System | 07 Aug 2020 22:50:43 |
| User entered 'POST MENOPAUSAL' | Janna Martinez (b) (4) | 07 Aug 2020 22:50:24 |
| | (b) (4) | |

US3062128

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:31:56 |
| User entered 'UN Jan 1988' | Janna Martinez (b) (4) | 07 Aug 2020 22:50:24 |
| | (b) (4) | |

US3062128

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:03:08

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 14:31:56 |
| User entered '0' | Janna Martinez (b) (4) (b) (4) | 07 Aug 2020 22:50:24 |

US3062128

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:03:08

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:31:56 |
| User entered 'Yes (Y)' | Janna Martinez (b) (4) | 07 Aug 2020 22:50:24 |
| | (b) (4) | |

US3062128

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 14:31:56 |
| User entered empty. | Janna Martinez (b) (4) (b) (4) | 07 Aug 2020 22:50:24 |

US3062128

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:03:08

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:31:56 |
| User entered '0' | Janna Martinez (b) (4) | 07 Aug 2020 22:50:24 |
| | (b) (4) | |

US3062128

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User entered 'Jan 1988' | System | 07 Aug 2020 22:50:24 |

US3062128

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User entered '1988' | System | 07 Aug 2020 22:50:24 |

US3062128

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User entered empty. | System | 07 Aug 2020 22:50:24 |

US3062128

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User entered empty. | System | 07 Aug 2020 22:50:24 |

US3062128

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:03:08

[Condition](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:31:56 |
| | (b) (4) | |
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Bone disorders (excl congenital and fractures), HLT: Metabolic bone disorders, PT: Osteopenia, LLT: Osteopenia - version MedDRA\\23.0. | Coder Import (b) (4) | 07 Aug 2020 22:52:19 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 07 Aug 2020 22:52:19 |
| | (b) (4) | |
| Data point term sent to Coder | System | 07 Aug 2020 22:51:45 |
| User entered 'OSTEOPENIA' | Janna Martinez (b) (4) | 07 Aug 2020 22:50:48 |
| | (b) (4) | |

US3062128

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:03:08

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:31:56 |
| User entered 'UN Jan 2010' | Janna Martinez (b) (4) | 07 Aug 2020 22:50:48 |
| | (b) (4) | |

US3062128

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:03:08

Start date completely unknown

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:31:56 |
| User entered '0' | Janna Martinez (b) (4) | 07 Aug 2020 22:50:48 |
| | (b) (4) | |

US3062128

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:03:08

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 14:31:56 |
| User entered 'Yes (Y)' | Janna Martinez (b) (4) (b) (4) | 07 Aug 2020 22:50:48 |

US3062128

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:31:56 |
| User entered empty. | Janna Martinez (b) (4) | 07 Aug 2020 22:50:48 |
| | (b) (4) | |

US3062128

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:03:08

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:31:56 |
| User entered '0' | Janna Martinez (b) (4) | 07 Aug 2020 22:50:48 |
| | (b) (4) | |

US3062128

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User entered 'Jan 2010' | System | 07 Aug 2020 22:50:48 |

US3062128

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User entered '2010' | System | 07 Aug 2020 22:50:48 |

US3062128

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User entered empty. | System | 07 Aug 2020 22:50:48 |

US3062128

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User entered empty. | System | 07 Aug 2020 22:50:48 |

US3062128

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:03:08

[Condition](#)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 07 Oct 2020 14:31:56 |
| User coded data point as SOC: Psychiatric disorders, HLGT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0. | Coder Import (b) (4) | 09 Sep 2020 16:36:41 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | (b) (4) | |
| Data point term sent to Coder | System | 09 Sep 2020 16:35:42 |
| User entered 'insomnia' | marissa Mueller (b) (4) | 09 Sep 2020 16:34:56 |
| | (b) (4) | |

US3062128

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:03:08

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 14:31:56 |
| User entered 'un Jan 2015' | marissa Mueller (b) (4) (b) (4) | 09 Sep 2020 16:34:56 |

US3062128

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:03:08

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 14:31:56 |
| User entered '0' | marissa Mueller (b) (4) (b) (4) | 09 Sep 2020 16:34:56 |

US3062128

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:03:08

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 14:31:56 |
| User entered 'Yes (Y)' | marissa Mueller (b) (4) (b) (4) | 09 Sep 2020 16:34:56 |

US3062128

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:31:56 |
| User entered empty. | marissa Mueller (b) (4) | 09 Sep 2020 16:34:56 |
| | (b) (4) | |

US3062128

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:03:08

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:31:56 |
| User entered '0' | marissa Mueller (b) (4) | 09 Sep 2020 16:34:56 |
| | (b) (4) | |

US3062128

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User entered 'Jan 2015' | System | 09 Sep 2020 16:34:56 |

US3062128

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User entered '2015' | System | 09 Sep 2020 16:34:56 |

US3062128

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User entered empty. | System | 09 Sep 2020 16:34:56 |

US3062128

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User entered empty. | System | 09 Sep 2020 16:34:56 |

US3062128

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:03:08

[Condition](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:31:56 |
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Generalized osteoarthritis - version MedDRA\\23.0. | Coder Import (b) (4) | 09 Sep 2020 16:37:48 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 09 Sep 2020 16:37:48 |
| Data point term sent to Coder | System | 09 Sep 2020 16:36:46 |
| User entered 'osteoarthritis, generalized' | marissa Mueller (b) (4) | 09 Sep 2020 16:36:16 |
| | (b) (4) | |

US3062128

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:31:56 |
| User entered 'un Jan 2015' | marissa Mueller (b) (4) | 09 Sep 2020 16:36:16 |
| | (b) (4) | |

US3062128

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:03:08

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 14:31:56 |
| User entered '0' | marissa Mueller (b) (4) (b) (4) | 09 Sep 2020 16:36:16 |

US3062128

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:03:08

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:31:56 |
| User entered 'Yes (Y)' | marissa Mueller (b) (4) | 09 Sep 2020 16:36:16 |
| | (b) (4) | |

US3062128

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 14:31:56 |
| User entered empty. | marissa Mueller (b) (4) | 09 Sep 2020 16:36:16 |
| | (b) (4) | |

US3062128

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:03:08

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:31:56 |
| User entered '0' | marissa Mueller (b) (4) | 09 Sep 2020 16:36:16 |
| | (b) (4) | |

US3062128

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User entered 'Jan 2015' | System | 09 Sep 2020 16:36:16 |

US3062128

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User entered '2015' | System | 09 Sep 2020 16:36:16 |

US3062128

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User entered empty. | System | 09 Sep 2020 16:36:16 |

US3062128

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User entered empty. | System | 09 Sep 2020 16:36:16 |

US3062128

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:08

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Sep 2020 02:24:46 |
| User entered 'Yes (Y)' | Janna Martinez (b) (4) | 07 Aug 2020 22:51:55 |
| | (b) (4) | |

US3062128

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:08

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Sep 2020 02:24:46 |
| User entered '06 Aug 2020' | Janna Martinez (b) (4) | 07 Aug 2020 22:51:55 |
| | (b) (4) | |

US3062128

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Oct 2020 15:16:27 |
| User closed query 'Per source height and weight collected at 15:32. Please verify and update if needed. ' (Site from CRA). | (b) (4), (b) (6) | 08 Oct 2020 15:16:26 |
| Query 'Per source height and weight collected at 15:32. Please verify and update if needed. ' answered with 'updated' (Site from CRA). | marissa Mueller (b) (4) | 07 Oct 2020 23:03:53 |
| DataPoint Un-verified. | (b) (4) | |
| | marissa Mueller (b) (4) | 07 Oct 2020 23:03:49 |
| | (b) (4) | |
| User entered '15:32' reason for change: Data Entry Error | marissa Mueller (b) (4) | 07 Oct 2020 23:03:49 |
| | (b) (4) | |
| User opened query 'Per source height and weight collected at 15:32. Please verify and update if needed. ' (Site from CRA). | (b) (4), (b) (6) | 07 Oct 2020 14:33:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Sep 2020 02:24:46 |
| User entered '15:29' | Janna Martinez (b) (4) | 07 Aug 2020 22:51:55 |
| | (b) (4) | |

US3062128

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User entered '06 Aug 2020 15:32' | System | 07 Oct 2020 23:03:49 |
| User entered '06 Aug 2020 15:29' | System | 07 Aug 2020 22:51:55 |

US3062128

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:08

Height (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Sep 2020 02:24:46 |
| User entered '170.5' cm | Janna Martinez (b) (4) | 07 Aug 2020 22:51:55 |
| DataPoint set to visible. | System | 06 Aug 2020 21:59:42 |

US3062128

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:08

Weight (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Sep 2020 02:24:46 |
| User entered '79.1' kg | Janna Martinez (b) (4) | 07 Aug 2020 22:51:55 |
| DataPoint set to visible. | (b) (4) System | 06 Aug 2020 21:59:42 |

US3062128

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:08

BMI (xxx.x)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| Amendment Manager: User entered '27.20995' | System | 16 Sep 2020 23:46:28 |
| User entered '27.2' | System | 07 Aug 2020 22:51:55 |
| DataPoint set to visible. | System | 06 Aug 2020 21:59:42 |

US3062128

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:08

[BMI units](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User entered 'kg/m2' | System | 07 Aug 2020 22:51:55 |
| DataPoint set to visible. | System | 06 Aug 2020 21:59:42 |

US3062128

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:08

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Sep 2020 02:24:46 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Brianna Burton (b) (4) (b) (4) | 26 Aug 2020 16:55:13 |
| User entered '98.7' F | Janna Martinez (b) (4) (b) (4) | 07 Aug 2020 22:51:55 |

US3062128

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:08

[Route of measurement](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Sep 2020 02:24:46 |
| User entered empty; reason for change Data Entry Error | Brianna Burton (b) (4) | 26 Aug 2020 16:55:13 |
| | (b) (4) | |
| User entered 'Oral (Oral)' | Janna Martinez (b) (4) | 07 Aug 2020 22:51:55 |
| | (b) (4) | |

US3062128

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:08

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Sep 2020 02:24:46 |
| User entered empty. | Janna Martinez (b) (4) (b) (4) | 07 Aug 2020 22:51:55 |

US3062128

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:08

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Sep 2020 02:24:46 |
| | | |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Brianna Burton (b) (4) | 26 Aug 2020 16:55:13 |
| | (b) (4) | |
| User entered '75' | Janna Martinez (b) (4) | 07 Aug 2020 22:51:55 |
| | (b) (4) | |

US3062128

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:08

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User entered 'bpm' | System | 07 Aug 2020 22:51:55 |

US3062128

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Sep 2020 02:24:46 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Brianna Burton (b) (4) | 26 Aug 2020 16:55:13 |
| User entered '16' | Janna Martinez (b) (4) | 07 Aug 2020 22:51:55 |
| | (b) (4) | |

US3062128

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:08

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User entered 'breaths/min' | System | 07 Aug 2020 22:51:55 |

US3062128

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Sep 2020 02:24:46 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Brianna Burton (b) (4) | 26 Aug 2020 16:55:13 |
| User entered '98' | Janna Martinez (b) (4) | 07 Aug 2020 22:51:55 |
| | (b) (4) | |

US3062128

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:08

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User entered 'mmHg' | System | 07 Aug 2020 22:51:55 |

US3062128

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:08

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Sep 2020 02:24:46 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Brianna Burton (b) (4) (b) (4) | 26 Aug 2020 16:55:13 |
| User entered '55' | Janna Martinez (b) (4) (b) (4) | 07 Aug 2020 22:51:55 |

US3062128

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:08

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User entered 'mmHg' | System | 07 Aug 2020 22:51:55 |

US3062128

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:08

Height (derived)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| | | |

US3062128

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:08

[Weight \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| | | |

US3062128

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:03:08

Was the physical examination performed?

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Sep 2020 02:24:57 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Brianna Burton (b) (4) (b) (4) | 26 Aug 2020 16:55:39 |
| User entered 'No (N)' | Janna Martinez (b) (4) (b) (4) | 07 Aug 2020 22:51:59 |

US3062128

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:03:08

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Sep 2020 02:24:57 |
| Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System). | (b) (4), (b) (6) | 06 Sep 2020 13:24:43 |
| User opened query 'The Physical Examination Date isSystem prior to the Screening Visit Date. Please review and reconcile.' (Site from System). | | 03 Sep 2020 17:23:19 |
| User entered '06 Aug 2020' reason for change: Data Entry Error | Brianna Burton (b) (4) | 26 Aug 2020 16:55:39 |
| User entered empty. | Janna Martinez (b) (4) | 07 Aug 2020 22:51:59 |
| | (b) (4) | |

US3062128

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:03:08

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Sep 2020 02:25:04 |
| User entered '6 Aug 2020' | Janna Martinez (b) (4) | 07 Aug 2020 22:52:14 |
| | (b) (4) | |

US3062128

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:03:08

[Is the participant of childbearing potential?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Sep 2020 02:25:04 |
| User entered 'No (N)' | Janna Martinez (b) (4) | 07 Aug 2020 22:52:14 |
| | (b) (4) | |

US3062128

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:03:08

If No, what is the reason?

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Sep 2020 02:25:04 |
| User closed query 'Surgically sterile has not been entered, however date of surgery is provided, or Date of surgery unknown is checked. Please correct.' (Site from System). | System | 07 Aug 2020 22:52:34 |
| User opened query 'Surgically sterile has not been entered, however date of surgery is provided, or Date of surgery unknown is checked. Please correct.' (Site from System). | System | 07 Aug 2020 22:52:14 |
| User entered 'Post-menopausal (POST-MENOPAUSAL)' | Janna Martinez (b) (4) (b) (4) | 07 Aug 2020 22:52:14 |

US3062128

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:03:08

If Partner medically sterile or Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Sep 2020 02:25:04 |
| User entered empty. | Janna Martinez (b) (4) (b) (4) | 07 Aug 2020 22:52:14 |

US3062128

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:03:08

If Surgically sterile, date of surgery (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Sep 2020 02:25:04 |
| User entered empty; reason for change Data Entry Error | Janna Martinez (b) (4) | 07 Aug 2020 22:52:34 |
| User entered 'UN Jan 1988' | Janna Martinez (b) (4) | 07 Aug 2020 22:52:14 |

US3062128

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:03:08

Date of surgery unknown

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Sep 2020 02:25:04 |
| User entered '0' | Janna Martinez (b) (4) (b) (4) | 07 Aug 2020 22:52:14 |

US3062128

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:03:08

If Post-menopausal, date of last menstruation (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Sep 2020 02:25:04 |
| User closed query 'Post-menopausal has been entered, however date of last menstruation is missing. Please provide.' (Site from System). | System | 07 Aug 2020 22:52:34 |
| User entered 'UN Jan 1988' reason for change: Data Entry Error | Janna Martinez (b) (4) | 07 Aug 2020 22:52:34 |
| | (b) (4) | |
| User opened query 'Post-menopausal has been entered, however date of last menstruation is missing. Please provide.' (Site from System). | System | 07 Aug 2020 22:52:14 |
| User entered empty. | Janna Martinez (b) (4) | 07 Aug 2020 22:52:14 |
| | (b) (4) | |

US3062128

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:03:08

[Date of last menstruation unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Sep 2020 02:25:04 |
| User entered '0' | Janna Martinez (b) (4) | 07 Aug 2020 22:52:14 |
| | (b) (4) | |

US3062128

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:03:08

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:32:26 |
| User entered 'No (N)' | Janna Martinez (b) (4) | 07 Aug 2020 22:53:02 |
| | (b) (4) | |

US3062128

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:03:08

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:32:26 |
| User entered 'No (N)' | Janna Martinez (b) (4) | 07 Aug 2020 22:53:02 |
| | (b) (4) | |

US3062128

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:03:08

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) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:32:26 |
| User entered 'No (N)' | Janna Martinez (b) (4) | 07 Aug 2020 22:53:02 |
| | (b) (4) | |

US3062128

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:03:08

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) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:32:26 |
| User entered 'No (N)' | Janna Martinez (b) (4) | 07 Aug 2020 22:53:02 |
| | (b) (4) | |

US3062128

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:03:08

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:32:26 |
| User entered 'No (N)' | Janna Martinez (b) (4) | 07 Aug 2020 22:53:02 |
| | (b) (4) | |

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:03:08

[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) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:32:26 |
| User entered 'No (N)' | Janna Martinez (b) (4) | 07 Aug 2020 22:53:02 |
| | (b) (4) | |

US3062128

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:03:08

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) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:32:26 |
| User entered 'No (N)' | Janna Martinez (b) (4) | 07 Aug 2020 22:53:02 |

US3062128

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:03:08

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) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:32:26 |
| User entered 'No (N)' | Janna Martinez (b) (4) | 07 Aug 2020 22:53:02 |
| | (b) (4) | |

US3062128

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:03:08

[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) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:32:26 |
| User entered 'No (N)' | Janna Martinez (b) (4) | 07 Aug 2020 22:53:02 |
| | (b) (4) | |

US3062128

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:03:08

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) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:32:26 |
| User entered 'No (N)' | Janna Martinez (b) (4) | 07 Aug 2020 22:53:02 |
| | (b) (4) | |

US3062128

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:03:08

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) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:32:26 |
| User entered 'No (N)' | Janna Martinez (b) (4) | 07 Aug 2020 22:53:02 |
| | (b) (4) | |

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:03:08

[Other](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:32:26 |
| User entered 'No (N)' | Janna Martinez (b) (4) | 07 Aug 2020 22:53:02 |
| | (b) (4) | |

US3062128

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:03:08

[Specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:32:26 |
| User entered empty. | Janna Martinez (b) (4) | 07 Aug 2020 22:53:02 |
| | (b) (4) | |

US3062128

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:03:08

No Risk Identified

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| | (b) (4) | |
| User entered '0' | Janna Martinez (b) (4) | 07 Aug 2020 22:53:02 |
| | (b) (4) | |

US3062128

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:03:08

Resides in Nursing Home or Assisted Living Facility

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:32:26 |
| User entered '0' | Janna Martinez (b) (4) | 07 Aug 2020 22:53:02 |
| | (b) (4) | |

US3062128

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:03:08

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) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:32:26 |
| User entered '0' | Janna Martinez (b) (4) | 07 Aug 2020 22:53:02 |

US3062128

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:03:08

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) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:32:26 |
| User entered '0' | Janna Martinez (b) (4) | 07 Aug 2020 22:53:02 |
| | (b) (4) | |

US3062128

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:03:08

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) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:32:26 |
| User entered '0' | Janna Martinez (b) (4) | 07 Aug 2020 22:53:02 |
| | (b) (4) | |

US3062128

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:32:26 |
| User entered 'I' | Janna Martinez (b) (4) | 07 Aug 2020 22:53:02 |
| | (b) (4) | |

US3062128

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:03:08

Other

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| | (b) (4) | |
| User entered '0' | Janna Martinez (b) (4) | 07 Aug 2020 22:53:02 |
| | (b) (4) | |

US3062128

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:03:08

[Specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 11:16:01 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:32:26 |
| User entered empty. | Janna Martinez (b) (4) | 07 Aug 2020 22:53:02 |
| | (b) (4) | |

US3062128

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:03:08

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:48 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Sep 2020 17:13:53 |
| User entered 'Yes (Y)' | Riley King (b) (4) | 06 Aug 2020 22:00:08 |
| | (b) (4) | |

US3062128

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:03:08

Visit date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:48 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Sep 2020 17:13:53 |
| User entered '06 Aug 2020' | Riley King (b) (4) | 06 Aug 2020 22:00:08 |

US3062128

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|--------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:48 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Sep 2020 17:13:53 |
| User entered 'Clinic (Clinic)' | Riley King (b) (4) | 06 Aug 2020 22:00:08 |

US3062128

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:03:08

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User entered 'VISIT1' | System | 06 Aug 2020 22:00:08 |

US3062128

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Sep 2020 17:43:55 |
| User entered '06 AUG 2020' | RWS_ENDPOINT ENDPOINT (b) (4) | 06 Aug 2020 21:24:19 |

US3062128

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:03:08

What was the participant's randomization number?

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 30 Mar 2021 19:52:08 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System). | (b) (4) System | 21 Aug 2020 02:42:26 |
| Amendment Manager: Data point set to conformant. | System | 21 Aug 2020 02:42:26 |
| User opened query 'Data entered is non-conformant. Please correct.' (Site from System). | System | 06 Aug 2020 21:24:19 |
| User entered '185026' (non-conformant). | RWS_ENDPOINT ENDPOINT (b) (4) | 06 Aug 2020 21:24:19 |

US3062128

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|-------------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Sep 2020 17:43:57 |
| User entered '>=65 years (3)' | RWS_ENDPOINT ENDPOINT (b) (4) | 06 Aug 2020 21:24:19 |

US3062128

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:03:08

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) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Sep 2020 17:44:01 |
| User entered 'No (N)' | Riley King (b) (4) | 06 Aug 2020 22:00:41 |

US3062128

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:03:08

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) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Sep 2020 17:44:03 |
| User entered 'No (N)' | Riley King (b) (4) | 06 Aug 2020 22:00:41 |

US3062128

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Sep 2020 17:44:07 |
| User entered 'No (N)' | Riley King (b) (4) | 06 Aug 2020 22:00:41 |

US3062128

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:03:08

Diabetes (Type I, Type 2, or gestational)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Sep 2020 17:44:09 |
| User entered 'No (N)' | Riley King (b) (4) | 06 Aug 2020 22:00:41 |

US3062128

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:03:08

[Liver Disease](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Sep 2020 17:44:10 |
| User entered 'No (N)' | Riley King (b) (4) | 06 Aug 2020 22:00:41 |

US3062128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:03:08

Height

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:48 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:41:01 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Brianna Burton (b) (4) | 26 Aug 2020 16:55:24 |
| User entered '170.5' cm | (b) (4) | |
| | Janna Martinez (b) (4) | 07 Aug 2020 22:54:43 |
| | (b) (4) | |

US3062128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:03:08

Weight

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:48 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:41:02 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Brianna Burton (b) (4) | 26 Aug 2020 16:55:24 |
| User entered '79.1' kg | Janna Martinez (b) (4) | 07 Aug 2020 22:54:43 |
| | (b) (4) | |

US3062128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:03:08

Height

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:48 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:41:01 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Brianna Burton (b) (4) | 26 Aug 2020 16:55:24 |
| User entered '170.5' cm | (b) (4) | |
| | Janna Martinez (b) (4) | 07 Aug 2020 22:54:43 |
| | (b) (4) | |

US3062128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:03:08

Weight

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:48 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:41:02 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Brianna Burton (b) (4) | 26 Aug 2020 16:55:24 |
| User entered '79.1' kg | Janna Martinez (b) (4) | 07 Aug 2020 22:54:43 |

US3062128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:08

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User accepted default value 'Pre-Dose (PREDOSE)' | Janna Martinez (b) (4) | 07 Aug 2020 22:54:43 |
| | (b) (4) | |

US3062128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:08

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:48 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:40:38 |
| User entered 'Yes (Y)' | Janna Martinez (b) (4) | 07 Aug 2020 22:54:43 |
| | (b) (4) | |

US3062128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:08

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:48 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:40:40 |
| User entered '06 Aug 2020' | Janna Martinez (b) (4) | 07 Aug 2020 22:54:43 |
| | (b) (4) | |

US3062128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:48 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:40:43 |
| User entered '15:29' | Janna Martinez (b) (4) | 07 Aug 2020 22:54:43 |
| | (b) (4) | |

US3062128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User entered '06 Aug 2020 15:29' | System | 07 Aug 2020 22:54:43 |

US3062128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:08

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:48 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Oct 2020 15:16:54 |
| User closed query 'Per source temperature is 98.7 F. Please verify and update if needed. ' (Site from CRA). | (b) (4), (b) (6) | 08 Oct 2020 15:16:52 |
| Query 'Per source temperature is 98.7 F. Please verify and update if needed. ' answered with 'updated' (Site from CRA). | marissa Mueller (b) (4) | 07 Oct 2020 23:05:53 |
| User entered '98.7' F reason for change: Data Entry Error | marissa Mueller (b) (4) | 07 Oct 2020 23:05:46 |
| | (b) (4) | |
| User opened query 'Per source temperature is 98.7 F. Please verify and update if needed. ' (Site from CRA). | (b) (4), (b) (6) | 07 Oct 2020 14:40:01 |
| User entered '97.5' F | Janna Martinez (b) (4) | 07 Aug 2020 22:54:43 |
| | (b) (4) | |

US3062128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:08

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:48 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:40:44 |
| User entered 'Oral (Oral)' | Janna Martinez (b) (4) | 07 Aug 2020 22:54:43 |
| | (b) (4) | |

US3062128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:08

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:48 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:40:46 |
| User entered empty. | Janna Martinez (b) (4) | 07 Aug 2020 22:54:43 |
| | (b) (4) | |

US3062128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:08

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:48 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:40:48 |
| User entered '75' | Janna Martinez (b) (4) | 07 Aug 2020 22:54:43 |
| | (b) (4) | |

US3062128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:08

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User entered 'bpm' | System | 07 Aug 2020 22:54:43 |

US3062128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:48 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:40:49 |
| User entered '16' | Janna Martinez (b) (4) | 07 Aug 2020 22:54:43 |
| | (b) (4) | |

US3062128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:08

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User entered 'breaths/min' | System | 07 Aug 2020 22:54:43 |

US3062128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:08

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:48 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:40:51 |
| User entered '98' | Janna Martinez (b) (4) | 07 Aug 2020 22:54:43 |
| | (b) (4) | |

US3062128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:08

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User entered 'mmHg' | System | 07 Aug 2020 22:54:43 |

US3062128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:08

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:48 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:40:53 |
| User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System). | (b) (4), (b) (6) | 23 Sep 2020 09:06:58 |
| Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS, per Sub-I ' (Site from System). | Sherry Henning (b) (4) | 21 Sep 2020 17:33:21 |
| Amendment Manager: User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System). | System | 16 Sep 2020 23:46:28 |
| User entered '55' | Janna Martinez (b) (4) | 07 Aug 2020 22:54:43 |

US3062128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:08

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User entered 'mmHg' | System | 07 Aug 2020 22:54:43 |

US3062128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:03:08

Height

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:48 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:41:01 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Brianna Burton (b) (4) | 26 Aug 2020 16:55:24 |
| User entered '170.5' cm | (b) (4) | |
| | Janna Martinez (b) (4) | 07 Aug 2020 22:54:43 |
| | (b) (4) | |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:03:08

Weight

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:48 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:41:02 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Brianna Burton (b) (4) | 26 Aug 2020 16:55:24 |
| User entered '79.1' kg | Janna Martinez (b) (4) | 07 Aug 2020 22:54:43 |
| | (b) (4) | |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:08

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User accepted default value 'Post-Dose (POSTDOSE)' | Janna Martinez (b) (4) | 07 Aug 2020 22:54:43 |
| | (b) (4) | |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:08

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:48 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:41:04 |
| User entered 'Yes (Y)' | Janna Martinez (b) (4) | 07 Aug 2020 22:54:43 |
| | (b) (4) | |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:08

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:48 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:41:07 |
| User entered '06 Aug 2020' | Janna Martinez (b) (4) | 07 Aug 2020 22:54:43 |
| | (b) (4) | |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:48 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:41:10 |
| User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System). | (b) (4), (b) (6) | 12 Aug 2020 07:15:09 |
| Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'DATA CORRECT AS ENTERED' (Site from System). | Janna Martinez (b) (4) | 07 Aug 2020 22:54:52 |
| | (b) (4) | |
| User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System). | | 07 Aug 2020 22:54:43 |
| User entered '17:19' | Janna Martinez (b) (4) | 07 Aug 2020 22:54:43 |
| | (b) (4) | |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User entered '06 Aug 2020 17:19' | System | 07 Aug 2020 22:54:43 |

US3062128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:08

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:48 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:41:17 |
| User closed query 'Source states temp is 97.5. Please verify and update as needed. ' (Site from CRA). | (b) (4), (b) (6) | 07 Oct 2020 14:41:15 |
| Query 'Source states temp is 97.5. Please verify and update as needed. ' answered with 'DATA CORRECTED' (Site from CRA). | Janna Martinez (b) (4) | 23 Sep 2020 19:31:00 |
| User entered '97.5' F reason for change: Data Entry Error | (b) (4) | |
| | Janna Martinez (b) (4) | 23 Sep 2020 19:30:54 |
| | (b) (4) | |
| User opened query 'Source states temp is 97.5. Please verify and update as needed. ' (Site from CRA). | (b) (4), (b) (6) | 23 Sep 2020 17:47:11 |
| User entered '98.7' F | Janna Martinez (b) (4) | 07 Aug 2020 22:54:43 |
| | (b) (4) | |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:08

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:48 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Sep 2020 17:48:07 |
| User entered 'Oral (Oral)' | Janna Martinez (b) (4) | 07 Aug 2020 22:54:43 |
| | (b) (4) | |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:08

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:48 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Sep 2020 17:48:09 |
| User entered empty. | Janna Martinez (b) (4) | 07 Aug 2020 22:54:43 |
| | (b) (4) | |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:08

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:48 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Sep 2020 17:48:11 |
| User entered '65' | Janna Martinez (b) (4) | 07 Aug 2020 22:54:43 |
| | (b) (4) | |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:08

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User entered 'bpm' | System | 07 Aug 2020 22:54:43 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:48 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Sep 2020 17:48:12 |
| User entered '16' | Janna Martinez (b) (4) | 07 Aug 2020 22:54:43 |
| | (b) (4) | |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:08

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User entered 'breaths/min' | System | 07 Aug 2020 22:54:43 |

US3062128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:08

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:48 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Sep 2020 17:48:14 |
| User entered '155' | Janna Martinez (b) (4) | 07 Aug 2020 22:54:43 |

US3062128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:08

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User entered 'mmHg' | System | 07 Aug 2020 22:54:43 |

US3062128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:08

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:48 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Sep 2020 17:48:16 |
| User entered '75' | Janna Martinez (b) (4) | 07 Aug 2020 22:54:43 |

US3062128

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:08

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User entered 'mmHg' | System | 07 Aug 2020 22:54:43 |

US3062128

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:03:08

Was the physical examination performed?

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Sep 2020 17:48:26 |
| User entered 'No (N)' reason for change: Data Entry Error | Brianna Burton (b) (4) | 26 Aug 2020 16:55:48 |
| User entered 'Yes (Y)' | Janna Martinez (b) (4) | 07 Aug 2020 22:55:08 |
| | (b) (4) | |

US3062128

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:03:08

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Sep 2020 17:48:26 |
| User entered empty; reason for change Data Entry Error | Brianna Burton (b) (4) | 26 Aug 2020 16:55:48 |
| | (b) (4) | |
| User entered '6 Aug 2020' | Janna Martinez (b) (4) | 07 Aug 2020 22:55:08 |
| | (b) (4) | |

US3062128

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:03:08

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Sep 2020 17:49:14 |
| User entered 'Yes (Y)' | Riley King (b) (4) | 06 Aug 2020 22:01:06 |
| | (b) (4) | |

US3062128

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:03:08

If No, reason not given

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Sep 2020 17:49:14 |
| User entered empty. | Riley King (b) (4) | 06 Aug 2020 22:01:06 |

US3062128

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:03:08

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) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Sep 2020 17:49:14 |
| User entered empty. | Riley King (b) (4) | 06 Aug 2020 22:01:06 |

US3062128

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:03:08

[What was the study treatment?](#)

| Audit | User | Time (GMT) |
|-------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User entered 'MRNA-1273 OR PLACEBO' | System | 06 Aug 2020 22:01:06 |

US3062128

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:03:08

What was the treatment date? (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Sep 2020 17:49:14 |
| User entered '06 Aug 2020' | Riley King (b) (4) | 06 Aug 2020 22:01:06 |

US3062128

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Sep 2020 17:49:14 |
| User entered '16:48' | Riley King (b) (4) | 06 Aug 2020 22:01:06 |
| | (b) (4) | |

US3062128

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User entered '06 Aug 2020 16:48' | System | 06 Aug 2020 22:01:06 |

US3062128

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|------------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Sep 2020 17:49:14 |
| User entered 'Left Arm (LEFT ARM)' | Riley King (b) (4) | 06 Aug 2020 22:01:06 |

US3062128

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Sep 2020 17:49:14 |
| User entered 'ONCE' | System | 06 Aug 2020 22:01:06 |

US3062128

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:03:08

What was the route of administration for the study treatment?

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User entered 'INTRAMUSCULAR' | System | 06 Aug 2020 22:01:06 |

US3062128

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:03:08

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Sep 2020 17:49:31 |
| User entered 'Yes (Y)' | Janna Martinez (b) (4) | 07 Aug 2020 22:55:29 |

US3062128

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:03:08

Collection date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Sep 2020 17:49:31 |
| User entered '6 Aug 2020' | Janna Martinez (b) (4) | 07 Aug 2020 22:55:29 |

US3062128

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:03:08

[Collection time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Sep 2020 17:49:31 |
| User entered '15:57' | Janna Martinez (b) (4) | 07 Aug 2020 22:55:29 |
| | (b) (4) | |

US3062128

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:03:08

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User entered '6 Aug 2020 15:57' | System | 07 Aug 2020 22:55:29 |

US3062128

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:03:08

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Sep 2020 17:53:56 |
| User entered '6 Aug 2020' | Janna Martinez (b) (4) | 07 Aug 2020 22:55:40 |

US3062128

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:03:08

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | Janna Martinez (b) (4) | 07 Aug 2020 22:55:40 |
| | (b) (4) | |

US3062128

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:03:08

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Sep 2020 17:53:54 |
| User entered 'Yes (Y)' | Janna Martinez (b) (4) | 07 Aug 2020 22:55:40 |

US3062128

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:03:08

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:37:43 |
| User closed query 'Source states time at 15:52. Please verify and update.' (Site from CRA). | (b) (4), (b) (6) | 07 Oct 2020 14:37:42 |
| Query 'Source states time at 15:52. Please verify and update.' answered with 'DATA CORRECTED' (Site from CRA). | Janna Martinez (b) (4) | 23 Sep 2020 19:30:10 |
| User entered '15:52' reason for change: Data Entry Error | (b) (4) | |
| | Janna Martinez (b) (4) | 23 Sep 2020 19:30:04 |
| | (b) (4) | |
| User opened query 'Source states time at 15:52. Please verify and update.' (Site from CRA). | (b) (4), (b) (6) | 23 Sep 2020 17:53:48 |
| User entered '15:22' | Janna Martinez (b) (4) | 07 Aug 2020 22:55:40 |
| | (b) (4) | |

US3062128

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:03:08

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User entered '6 Aug 2020 15:52' | System | 23 Sep 2020 19:30:04 |
| User entered '6 Aug 2020 15:22' | System | 07 Aug 2020 22:55:40 |

US3062128

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:03:08

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | Janna Martinez (b) (4) | 07 Aug 2020 22:55:40 |
| | (b) (4) | |

US3062128

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:03:08

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Sep 2020 17:54:08 |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 07 Aug 2020 22:55:45 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 07 Aug 2020 22:55:45 |
| User entered 'No (N)' reason for change: Data Entry Error | Janna Martinez (b) (4) | 07 Aug 2020 22:55:45 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 07 Aug 2020 22:55:40 |
| User entered empty. | Janna Martinez (b) (4) | 07 Aug 2020 22:55:40 |

US3062128

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:03:08

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Sep 2020 17:54:08 |
| User entered empty. | Janna Martinez (b) (4) | 07 Aug 2020 22:55:40 |

US3062128

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:03:08

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User entered empty. | System | 07 Aug 2020 22:55:40 |

US3062128

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:03:08

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Sep 2020 17:54:13 |
| User entered 'Yes (Y)' | Janna Martinez (b) (4) | 07 Aug 2020 22:55:51 |
| | (b) (4) | |

US3062128

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:03:08

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User entered 'I' | System | 07 Aug 2020 22:55:51 |

US3062128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| Data entry locked. | System | 06 Aug 2020 22:01:06 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 06 Aug 2020 22:01:06 |

US3062128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:03:08

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-06T17:28:41', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'bc6020d2-cc14-460b-aad1-6eec9fd64fcf' | System | 06 Aug 2020 22:29:35 |
| User entered 'Yes (Y)' | System | 06 Aug 2020 22:29:35 |

US3062128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:03:08

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-06T17:28:49', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'bc6020d2-cc14-460b-aad1-6eec9fd64fcf' | System | 06 Aug 2020 22:29:35 |
| User entered '97.5' | System | 06 Aug 2020 22:29:35 |

US3062128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-06T17:28:57', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'bc6020d2-cc14-460b-aad1-6eec9fd64fcf' | System | 06 Aug 2020 22:29:35 |
| User entered 'Yes (Y)' | System | 06 Aug 2020 22:29:35 |

US3062128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|--|--|--|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| User closed query 'Requery :As per query response the concomitant medication section has been updated, kindly note as per the solicited section,medication was taken on day 1 for fever and pain, but there is no corresponding medication with the same start date in concomitant medication section' (Site from DM). Query 'Requery :As per query response the concomitant medication section has been updated, kindly note as per the solicited section,medication was taken on day 1 for fever and pain, but there is no corresponding medication with the same start date in concomitant medication section' answered with 'ibuprofen reported ' (Site from DM). | (b) (4), (b) (6) marissa Mueller (b) (4) (b) (4) | 19 Aug 2020 06:25:17 17 Aug 2020 23:00:34 |
| User opened query 'Requery :As per query response the concomitant medication section has been updated, kindly note as per the solicited section,medication was taken on day 1 for fever and pain, but there is no corresponding medication with the same start date in concomitant medication section' (Site from DM). | (b) (4), (b) (6) | 17 Aug 2020 11:37:12 |
| User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'update' (Site from System). | (b) (4), (b) (6) marissa Mueller (b) (4) (b) (4) | 17 Aug 2020 11:36:56 13 Aug 2020 21:30:03 |
| User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). | System | 06 Aug 2020 22:29:35 |

US3062128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-06T17:29:06', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'bc6020d2-cc14-460b-aad1-6eec9fd64fcf' | System | 06 Aug 2020 22:29:35 |
| User entered '1' | System | 06 Aug 2020 22:29:35 |

US3062128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:03:08

To **PREVENT** pain or fever from occurring

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-06T17:29:06', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'bc6020d2-cc14-460b-aad1-6eec9fd64fcf' | System | 06 Aug 2020 22:29:35 |
| User entered '0' | System | 06 Aug 2020 22:29:35 |

US3062128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:03:08

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-06T17:29:29', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'bc6020d2-cc14-460b-aad1-6eec9fd64fcf' | System | 06 Aug 2020 22:29:35 |
| User entered '06 Aug 2020 17:29' | System | 06 Aug 2020 22:29:35 |

US3062128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:03:08

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| User entered '06 Aug 2020 17:08' | System | 06 Aug 2020 22:01:06 |

US3062128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:03:08

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| User entered '06 Aug 2020 19:38' | System | 06 Aug 2020 22:01:06 |

US3062128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| Data entry locked. | System | 06 Aug 2020 22:01:06 |
| User entered 'Day 1, after vaccination (at home)' | System | 06 Aug 2020 22:01:06 |

US3062128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:03:08

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-06T21:13:07', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '0b1fab2-ff38-49fc-8a9f-49730d822283' | System | 07 Aug 2020 02:13:29 |
| User entered 'Yes (Y)' | System | 07 Aug 2020 02:13:29 |

US3062128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:03:08

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-06T21:13:15', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '0b1fab2c-ff38-49fc-8a9f-49730d822283' | System | 07 Aug 2020 02:13:29 |
| User entered '96.8' | System | 07 Aug 2020 02:13:29 |

US3062128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-06T21:13:20', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '0b1fab2c-ff38-49fc-8a9f-49730d822283' | System | 07 Aug 2020 02:13:29 |
| User entered 'No (N)' | System | 07 Aug 2020 02:13:29 |

US3062128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:03:08

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-06T21:13:27', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '0b1fab2-ff38-49fc-8a9f-49730d822283' | System | 07 Aug 2020 02:13:29 |
| User entered '06 Aug 2020 21:13' | System | 07 Aug 2020 02:13:29 |

US3062128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:03:08

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| User entered '06 Aug 2020 20:33' | System | 06 Aug 2020 22:01:06 |

US3062128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:03:08

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| User entered '07 Aug 2020 11:59' | System | 06 Aug 2020 22:01:06 |

US3062128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| Data entry locked. | System | 06 Aug 2020 22:01:06 |
| User entered 'Day 2' | System | 06 Aug 2020 22:01:06 |

US3062128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:03:08

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-07T21:19:35', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '19f5efc5-f566-4009-933c-639b7b1c89c4' | System | 08 Aug 2020 02:19:58 |
| User entered 'Yes (Y)' | System | 08 Aug 2020 02:19:58 |

US3062128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:03:08

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-07T21:19:44', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '19f5efc5-f566-4009-933c-639b7b1c89c4' | System | 08 Aug 2020 02:19:58 |
| User entered '96.3' | System | 08 Aug 2020 02:19:58 |

US3062128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-07T21:19:49', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '19f5efc5-f566-4009-933c-639b7b1c89c4' | System | 08 Aug 2020 02:19:58 |
| User entered 'No (N)' | System | 08 Aug 2020 02:19:58 |

US3062128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:03:08

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-07T21:19:56', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '19f5efc5-f566-4009-933c-639b7b1c89c4' | System | 08 Aug 2020 02:19:58 |
| User entered '07 Aug 2020 21:19' | System | 08 Aug 2020 02:19:58 |

US3062128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:03:08

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| User entered '07 Aug 2020 12:00' | System | 06 Aug 2020 22:01:06 |

US3062128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:03:08

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| User entered '08 Aug 2020 11:59' | System | 06 Aug 2020 22:01:06 |

US3062128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| Data entry locked. | System | 06 Aug 2020 22:01:06 |
| User entered 'Day 3' | System | 06 Aug 2020 22:01:06 |

US3062128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:03:08

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-08T20:56:45', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '8bc97613-2514-4321-b83b-513e5c03b0de' | System | 09 Aug 2020 02:00:02 |
| User entered 'Yes (Y)' | System | 09 Aug 2020 02:00:02 |

US3062128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:03:08

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-08T20:59:48', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '8bc97613-2514-4321-b83b-513e5c03b0de' | System | 09 Aug 2020 02:00:02 |
| User entered '97.5' | System | 09 Aug 2020 02:00:02 |

US3062128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-08T20:59:53', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '8bc97613-2514-4321-b83b-513e5c03b0de' | System | 09 Aug 2020 02:00:02 |
| User entered 'No (N)' | System | 09 Aug 2020 02:00:02 |

US3062128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:03:08

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-08T20:59:59', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '8bc97613-2514-4321-b83b-513e5c03b0de' | System | 09 Aug 2020 02:00:02 |
| User entered '08 Aug 2020 20:59' | System | 09 Aug 2020 02:00:02 |

US3062128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:03:08

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| User entered '08 Aug 2020 12:00' | System | 06 Aug 2020 22:01:06 |

US3062128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:03:08

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| User entered '09 Aug 2020 11:59' | System | 06 Aug 2020 22:01:06 |

US3062128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| Data entry locked. | System | 06 Aug 2020 22:01:06 |
| User entered 'Day 4' | System | 06 Aug 2020 22:01:06 |

US3062128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:03:08

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-09T21:31:02', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'c6e92828-3b13-4317-8733-10f36586cd40' | System | 10 Aug 2020 02:31:19 |
| User entered 'Yes (Y)' | System | 10 Aug 2020 02:31:19 |

US3062128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:03:08

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-09T21:31:08', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'c6e92828-3b13-4317-8733-10f36586cd40' | System | 10 Aug 2020 02:31:19 |
| User entered '96.7' | System | 10 Aug 2020 02:31:19 |

US3062128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-09T21:31:12', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'c6e92828-3b13-4317-8733-10f36586cd40' | System | 10 Aug 2020 02:31:19 |
| User entered 'No (N)' | System | 10 Aug 2020 02:31:19 |

US3062128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:03:08

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-09T21:31:17', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'c6e92828-3b13-4317-8733-10f36586cd40' | System | 10 Aug 2020 02:31:19 |
| User entered '09 Aug 2020 21:31' | System | 10 Aug 2020 02:31:19 |

US3062128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:03:08

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| User entered '09 Aug 2020 12:00' | System | 06 Aug 2020 22:01:06 |

US3062128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:03:08

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| User entered '10 Aug 2020 11:59' | System | 06 Aug 2020 22:01:06 |

US3062128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| Data entry locked. | System | 06 Aug 2020 22:01:06 |
| User entered 'Day 5' | System | 06 Aug 2020 22:01:06 |

US3062128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:03:08

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-10T20:47:12', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'ce6f8533-8cd3-4ac6-b4db-5d679b257595' | System | 11 Aug 2020 01:47:34 |
| User entered 'Yes (Y)' | System | 11 Aug 2020 01:47:34 |

US3062128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:03:08

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-10T20:47:19', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'ce6f8533-8cd3-4ac6-b4db-5d679b257595' | System | 11 Aug 2020 01:47:34 |
| User entered '97.5' | System | 11 Aug 2020 01:47:34 |

US3062128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-10T20:47:24', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'ce6f8533-8cd3-4ac6-b4db-5d679b257595' | System | 11 Aug 2020 01:47:34 |
| User entered 'No (N)' | System | 11 Aug 2020 01:47:34 |

US3062128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:03:08

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-10T20:47:28', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'ce6f8533-8cd3-4ac6-b4db-5d679b257595' | System | 11 Aug 2020 01:47:34 |
| User entered '10 Aug 2020 20:47' | System | 11 Aug 2020 01:47:34 |

US3062128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:03:08

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| User entered '10 Aug 2020 12:00' | System | 06 Aug 2020 22:01:06 |

US3062128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:03:08

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| User entered '11 Aug 2020 11:59' | System | 06 Aug 2020 22:01:06 |

US3062128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| Data entry locked. | System | 06 Aug 2020 22:01:06 |
| User entered 'Day 6' | System | 06 Aug 2020 22:01:06 |

US3062128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:03:08

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-11T21:30:10', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '7755a823-f2cb-49b0-9af8-e5012ad4dd68' | System | 12 Aug 2020 02:30:31 |
| User entered 'Yes (Y)' | System | 12 Aug 2020 02:30:31 |

US3062128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:03:08

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-11T21:30:19', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '7755a823-f2cb-49b0-9af8-e5012ad4dd68' | System | 12 Aug 2020 02:30:31 |
| User entered '98.6' | System | 12 Aug 2020 02:30:31 |

US3062128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-11T21:30:23', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '7755a823-f2cb-49b0-9af8-e5012ad4dd68' | System | 12 Aug 2020 02:30:31 |
| User entered 'No (N)' | System | 12 Aug 2020 02:30:31 |

US3062128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:03:08

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-11T21:30:28', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '7755a823-f2cb-49b0-9af8-e5012ad4dd68' | System | 12 Aug 2020 02:30:31 |
| User entered '11 Aug 2020 21:30' | System | 12 Aug 2020 02:30:31 |

US3062128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:03:08

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| User entered '11 Aug 2020 12:00' | System | 06 Aug 2020 22:01:06 |

US3062128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:03:08

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| User entered '12 Aug 2020 11:59' | System | 06 Aug 2020 22:01:06 |

US3062128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| Data entry locked. | System | 06 Aug 2020 22:01:06 |
| User entered 'Day 7' | System | 06 Aug 2020 22:01:06 |

US3062128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:03:08

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-12T21:09:53', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'd4989bc1-db86-4da8-8720-485dbcf99579' | System | 13 Aug 2020 02:10:11 |
| User entered 'Yes (Y)' | System | 13 Aug 2020 02:10:11 |

US3062128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:03:08

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-12T21:09:59', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'd4989bc1-db86-4da8-8720-485dbcf99579' User entered '97.3' | System | 13 Aug 2020 02:10:11 |
| | System | 13 Aug 2020 02:10:11 |

US3062128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-12T21:10:03', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'd4989bc1-db86-4da8-8720-485dbcf99579' | System | 13 Aug 2020 02:10:11 |
| User entered 'No (N)' | System | 13 Aug 2020 02:10:11 |

US3062128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:03:08

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-12T21:10:07', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'd4989bc1-db86-4da8-8720-485dbcf99579' | System | 13 Aug 2020 02:10:11 |
| User entered '12 Aug 2020 21:10' | System | 13 Aug 2020 02:10:11 |

US3062128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:03:08

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| User entered '12 Aug 2020 12:00' | System | 06 Aug 2020 22:01:06 |

US3062128

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:03:08

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| User entered '13 Aug 2020 11:59' | System | 06 Aug 2020 22:01:06 |

US3062128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| Data entry locked. | System | 06 Aug 2020 22:01:06 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 06 Aug 2020 22:01:06 |

US3062128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:03:08

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-06T17:29:39', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '38f7c05e-312d-4dff-b386-f7a619dacb10' | System | 06 Aug 2020 22:30:17 |
| User entered 'None (1)' | System | 06 Aug 2020 22:30:17 |

US3062128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:03:08

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-06T17:29:49', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '38f7c05e-312d-4dff-b386-f7a619dacb10' | System | 06 Aug 2020 22:30:17 |
| User entered 'No (N)' | System | 06 Aug 2020 22:30:17 |

US3062128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-06T17:29:52', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '38f7c05e-312d-4dff-b386-f7a619dacb10' | System | 06 Aug 2020 22:30:17 |
| User entered 'No (N)' | System | 06 Aug 2020 22:30:17 |

US3062128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:03:08

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-06T17:29:58', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '38f7c05e-312d-4dff-b386-f7a619dacb10' | System | 06 Aug 2020 22:30:17 |
| User entered 'None (1)' | System | 06 Aug 2020 22:30:17 |

US3062128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:03:08

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-06T17:30:14', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '38f7c05e-312d-4dff-b386-f7a619dacb10' | System | 06 Aug 2020 22:30:17 |
| User entered '06 Aug 2020 17:30' | System | 06 Aug 2020 22:30:17 |

US3062128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:03:08

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| User entered '06 Aug 2020 17:08' | System | 06 Aug 2020 22:01:06 |

US3062128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:03:08

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| User entered '06 Aug 2020 19:38' | System | 06 Aug 2020 22:01:06 |

US3062128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| Data entry locked. | System | 06 Aug 2020 22:01:06 |
| User entered 'Day 1, after vaccination (at home)' | System | 06 Aug 2020 22:01:06 |

US3062128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:03:08

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-06T21:13:42', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'bbd94d2d-d458-4df1-94b3-4fe7b720fc66' | System | 07 Aug 2020 02:14:13 |
| User entered 'None (1)' | System | 07 Aug 2020 02:14:13 |

US3062128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:03:08

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-06T21:13:48', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'bbd94d2d-d458-4df1-94b3-4fe7b720fc66' | System | 07 Aug 2020 02:14:13 |
| User entered 'No (N)' | System | 07 Aug 2020 02:14:13 |

US3062128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-06T21:13:54', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'bbd94d2d-d458-4df1-94b3-4fe7b720fc66' | System | 07 Aug 2020 02:14:13 |
| User entered 'No (N)' | System | 07 Aug 2020 02:14:13 |

US3062128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:03:08

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-06T21:14:01', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'bbd94d2d-d458-4df1-94b3-4fe7b720fc66' | System | 07 Aug 2020 02:14:13 |
| User entered 'None (1)' | System | 07 Aug 2020 02:14:13 |

US3062128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:03:08

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-06T21:14:10', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'bbd94d2d-d458-4df1-94b3-4fe7b720fc66' | System | 07 Aug 2020 02:14:13 |
| User entered '06 Aug 2020 21:14' | System | 07 Aug 2020 02:14:13 |

US3062128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:03:08

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| User entered '06 Aug 2020 20:33' | System | 06 Aug 2020 22:01:06 |

US3062128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:03:08

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| User entered '07 Aug 2020 11:59' | System | 06 Aug 2020 22:01:06 |

US3062128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| Data entry locked. | System | 06 Aug 2020 22:01:06 |
| User entered 'Day 2' | System | 06 Aug 2020 22:01:06 |

US3062128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:03:08

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-07T21:20:02', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '7bbf4ddc-2927-46b0-a9e7-542a3bf20964' | System | 08 Aug 2020 02:20:42 |
| User entered 'None (1)' | System | 08 Aug 2020 02:20:42 |

US3062128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:03:08

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-07T21:20:12', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '7bbf4ddc-2927-46b0-a9e7-542a3bf20964' | System | 08 Aug 2020 02:20:42 |
| User entered 'No (N)' | System | 08 Aug 2020 02:20:42 |

US3062128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-07T21:20:16', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '7bbf4ddc-2927-46b0-a9e7-542a3bf20964' | System | 08 Aug 2020 02:20:42 |
| User entered 'No (N)' | System | 08 Aug 2020 02:20:42 |

US3062128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:03:08

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-07T21:20:20', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '7bbf4ddc-2927-46b0-a9e7-542a3bf20964' | System | 08 Aug 2020 02:20:42 |
| User entered 'None (1)' | System | 08 Aug 2020 02:20:42 |

US3062128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:03:08

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-07T21:20:27', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '7bbf4ddc-2927-46b0-a9e7-542a3bf20964' | System | 08 Aug 2020 02:20:42 |
| User entered '07 Aug 2020 21:20' | System | 08 Aug 2020 02:20:42 |

US3062128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:03:08

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| User entered '07 Aug 2020 12:00' | System | 06 Aug 2020 22:01:06 |

US3062128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:03:08

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| User entered '08 Aug 2020 11:59' | System | 06 Aug 2020 22:01:06 |

US3062128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| Data entry locked. | System | 06 Aug 2020 22:01:06 |
| User entered 'Day 3' | System | 06 Aug 2020 22:01:06 |

US3062128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:03:08

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-08T21:00:11', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'ca930cda-fe44-4136-8fef-58375a6f6ada' | System | 09 Aug 2020 02:00:31 |
| User entered 'None (1)' | System | 09 Aug 2020 02:00:31 |

US3062128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:03:08

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-08T21:00:15', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'ca930cda-fe44-4136-8fef-58375a6f6ada' | System | 09 Aug 2020 02:00:31 |
| User entered 'No (N)' | System | 09 Aug 2020 02:00:31 |

US3062128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-08T21:00:18', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'ca930cda-fe44-4136-8fef-58375a6f6ada' | System | 09 Aug 2020 02:00:31 |
| User entered 'No (N)' | System | 09 Aug 2020 02:00:31 |

US3062128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:03:08

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-08T21:00:21', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'ca930cda-fe44-4136-8fef-58375a6f6ada' | System | 09 Aug 2020 02:00:31 |
| User entered 'None (1)' | System | 09 Aug 2020 02:00:31 |

US3062128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:03:08

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-08T21:00:28', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'ca930cda-fe44-4136-8fef-58375a6f6ada' | System | 09 Aug 2020 02:00:31 |
| User entered '08 Aug 2020 21:00' | System | 09 Aug 2020 02:00:31 |

US3062128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:03:08

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| User entered '08 Aug 2020 12:00' | System | 06 Aug 2020 22:01:06 |

US3062128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:03:08

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| User entered '09 Aug 2020 11:59' | System | 06 Aug 2020 22:01:06 |

US3062128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| Data entry locked. | System | 06 Aug 2020 22:01:06 |
| User entered 'Day 4' | System | 06 Aug 2020 22:01:06 |

US3062128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:03:08

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-09T21:31:24', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'ef2f3986-cba0-4c66-b831-7f845780fe51' | System | 10 Aug 2020 02:31:42 |
| User entered 'None (1)' | System | 10 Aug 2020 02:31:42 |

US3062128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:03:08

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-09T21:31:28', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'ef2f3986-cba0-4c66-b831-7f845780fe51' | System | 10 Aug 2020 02:31:42 |
| User entered 'No (N)' | System | 10 Aug 2020 02:31:42 |

US3062128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-09T21:31:31', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'ef2f3986-cba0-4c66-b831-7f845780fe51' | System | 10 Aug 2020 02:31:42 |
| User entered 'No (N)' | System | 10 Aug 2020 02:31:42 |

US3062128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:03:08

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-09T21:31:34', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'ef2f3986-cba0-4c66-b831-7f845780fe51' | System | 10 Aug 2020 02:31:42 |
| User entered 'None (1)' | System | 10 Aug 2020 02:31:42 |

US3062128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:03:08

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-09T21:31:38', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'ef2f3986-cba0-4c66-b831-7f845780fe51' | System | 10 Aug 2020 02:31:42 |
| User entered '09 Aug 2020 21:31' | System | 10 Aug 2020 02:31:42 |

US3062128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:03:08

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| User entered '09 Aug 2020 12:00' | System | 06 Aug 2020 22:01:06 |

US3062128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:03:08

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| User entered '10 Aug 2020 11:59' | System | 06 Aug 2020 22:01:06 |

US3062128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| Data entry locked. | System | 06 Aug 2020 22:01:06 |
| User entered 'Day 5' | System | 06 Aug 2020 22:01:06 |

US3062128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:03:08

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-10T20:47:35', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '6407343c-abad-4b16-af4f-930e1848d6b1' | System | 11 Aug 2020 01:47:53 |
| User entered 'None (1)' | System | 11 Aug 2020 01:47:53 |

US3062128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:03:08

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-10T20:47:38', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '6407343c-abad-4b16-af4f-930e1848d6b1' | System | 11 Aug 2020 01:47:53 |
| User entered 'No (N)' | System | 11 Aug 2020 01:47:53 |

US3062128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-10T20:47:41', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '6407343c-abad-4b16-af4f-930e1848d6b1' | System | 11 Aug 2020 01:47:53 |
| User entered 'No (N)' | System | 11 Aug 2020 01:47:53 |

US3062128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:03:08

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-10T20:47:44', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '6407343c-abad-4b16-af4f-930e1848d6b1' | System | 11 Aug 2020 01:47:53 |
| User entered 'None (1)' | System | 11 Aug 2020 01:47:53 |

US3062128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:03:08

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-10T20:47:49', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '6407343c-abad-4b16-af4f-930e1848d6b1' | System | 11 Aug 2020 01:47:53 |
| User entered '10 Aug 2020 20:47' | System | 11 Aug 2020 01:47:53 |

US3062128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:03:08

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| User entered '10 Aug 2020 12:00' | System | 06 Aug 2020 22:01:06 |

US3062128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:03:08

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| User entered '11 Aug 2020 11:59' | System | 06 Aug 2020 22:01:06 |

US3062128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| Data entry locked. | System | 06 Aug 2020 22:01:06 |
| User entered 'Day 6' | System | 06 Aug 2020 22:01:06 |

US3062128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:03:08

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-11T21:30:33', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'bf05c34e-8ace-48ee-b1d6-575b39cb0589' | System | 12 Aug 2020 02:30:52 |
| User entered 'None (1)' | System | 12 Aug 2020 02:30:52 |

US3062128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-11T21:30:36', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'bf05c34e-8ace-48ee-b1d6-575b39cb0589' | System | 12 Aug 2020 02:30:52 |
| User entered 'No (N)' | System | 12 Aug 2020 02:30:52 |

US3062128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-11T21:30:39', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'bf05c34e-8ace-48ee-b1d6-575b39cb0589' | System | 12 Aug 2020 02:30:52 |
| User entered 'No (N)' | System | 12 Aug 2020 02:30:52 |

US3062128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:03:08

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-11T21:30:42', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'bf05c34e-8ace-48ee-b1d6-575b39cb0589' | System | 12 Aug 2020 02:30:52 |
| User entered 'None (1)' | System | 12 Aug 2020 02:30:52 |

US3062128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:03:08

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-11T21:30:47', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'bf05c34e-8ace-48ee-b1d6-575b39cb0589' | System | 12 Aug 2020 02:30:52 |
| User entered '11 Aug 2020 21:30' | System | 12 Aug 2020 02:30:52 |

US3062128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:03:08

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| User entered '11 Aug 2020 12:00' | System | 06 Aug 2020 22:01:06 |

US3062128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:03:08

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| User entered '12 Aug 2020 11:59' | System | 06 Aug 2020 22:01:06 |

US3062128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| Data entry locked. | System | 06 Aug 2020 22:01:06 |
| User entered 'Day 7' | System | 06 Aug 2020 22:01:06 |

US3062128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:03:08

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-12T21:10:11', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'fbf84e80-cd54-484f-9cc0-be292163ccf7' | System | 13 Aug 2020 02:10:30 |
| User entered 'None (1)' | System | 13 Aug 2020 02:10:30 |

US3062128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:03:08

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-12T21:10:15', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'fbf84e80-cd54-484f-9cc0-be292163ccf7' | System | 13 Aug 2020 02:10:30 |
| User entered 'No (N)' | System | 13 Aug 2020 02:10:30 |

US3062128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-12T21:10:18', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'fbf84e80-cd54-484f-9cc0-be292163ccf7' | System | 13 Aug 2020 02:10:30 |
| User entered 'No (N)' | System | 13 Aug 2020 02:10:30 |

US3062128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:03:08

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-12T21:10:21', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'fbf84e80-cd54-484f-9cc0-be292163ccf7' | System | 13 Aug 2020 02:10:30 |
| User entered 'None (1)' | System | 13 Aug 2020 02:10:30 |

US3062128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:03:08

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-12T21:10:28', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'fbf84e80-cd54-484f-9cc0-be292163ccf7' | System | 13 Aug 2020 02:10:30 |
| User entered '12 Aug 2020 21:10' | System | 13 Aug 2020 02:10:30 |

US3062128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:03:08

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| User entered '12 Aug 2020 12:00' | System | 06 Aug 2020 22:01:06 |

US3062128

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:03:08

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| User entered '13 Aug 2020 11:59' | System | 06 Aug 2020 22:01:06 |

US3062128

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| Data entry locked. | System | 06 Aug 2020 22:01:06 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 06 Aug 2020 22:01:06 |

US3062128

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:08

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-06T17:30:22', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'addb02c5-6b28-40bc-ae4f-2af80466c665' | System | 06 Aug 2020 22:31:05 |
| User entered 'None (0)' | System | 06 Aug 2020 22:31:05 |

US3062128

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:08

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-06T17:30:27', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'addb02c5-6b28-40bc-ae4f-2af80466c665' | System | 06 Aug 2020 22:31:05 |
| User entered 'None (0)' | System | 06 Aug 2020 22:31:05 |

US3062128

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:08

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-06T17:30:34', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'addb02c5-6b28-40bc-ae4f-2af80466c665' | System | 06 Aug 2020 22:31:05 |
| User entered 'None (0)' | System | 06 Aug 2020 22:31:05 |

US3062128

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:08

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-06T17:30:39', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'addb02c5-6b28-40bc-ae4f-2af80466c665' | System | 06 Aug 2020 22:31:05 |
| User entered 'None (0)' | System | 06 Aug 2020 22:31:05 |

US3062128

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:08

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-06T17:30:43', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'addb02c5-6b28-40bc-ae4f-2af80466c665' | System | 06 Aug 2020 22:31:05 |
| User entered 'None (0)' | System | 06 Aug 2020 22:31:05 |

US3062128

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:08

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-06T17:30:47', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'addb02c5-6b28-40bc-ae4f-2af80466c665' | System | 06 Aug 2020 22:31:05 |
| User entered 'None (0)' | System | 06 Aug 2020 22:31:05 |

US3062128

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-06T17:30:52', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'addb02c5-6b28-40bc-ae4f-2af80466c665' | System | 06 Aug 2020 22:31:05 |
| User entered 'No (N)' | System | 06 Aug 2020 22:31:05 |

US3062128

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:08

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-06T17:31:01', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'addb02c5-6b28-40bc-ae4f-2af80466c665' | System | 06 Aug 2020 22:31:05 |
| User entered '06 Aug 2020 17:31' | System | 06 Aug 2020 22:31:05 |

US3062128

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:08

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| User entered '06 Aug 2020 17:08' | System | 06 Aug 2020 22:01:06 |

US3062128

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:08

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| User entered '06 Aug 2020 19:38' | System | 06 Aug 2020 22:01:06 |

US3062128

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| Data entry locked. | System | 06 Aug 2020 22:01:06 |
| User entered 'Day 1, after vaccination (at home)' | System | 06 Aug 2020 22:01:06 |

US3062128

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:08

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-06T21:14:16', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '24b27a25-0488-4afe-8a9a-bdf0466ee196' | System | 07 Aug 2020 02:14:51 |
| User entered 'None (0)' | System | 07 Aug 2020 02:14:51 |

US3062128

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:08

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-06T21:14:21', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '24b27a25-0488-4afe-8a9a-bdf0466ee196' | System | 07 Aug 2020 02:14:51 |
| User entered 'None (0)' | System | 07 Aug 2020 02:14:51 |

US3062128

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:08

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-06T21:14:24', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '24b27a25-0488-4afe-8a9a-bdf0466ee196' | System | 07 Aug 2020 02:14:51 |
| User entered 'None (0)' | System | 07 Aug 2020 02:14:51 |

US3062128

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:08

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-06T21:14:28', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '24b27a25-0488-4afe-8a9a-bdf0466ee196' | System | 07 Aug 2020 02:14:51 |
| User entered 'None (0)' | System | 07 Aug 2020 02:14:51 |

US3062128

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:08

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-06T21:14:32', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '24b27a25-0488-4afe-8a9a-bdf0466ee196' | System | 07 Aug 2020 02:14:51 |
| User entered 'None (0)' | System | 07 Aug 2020 02:14:51 |

US3062128

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:08

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-06T21:14:35', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '24b27a25-0488-4afe-8a9a-bdf0466ee196' | System | 07 Aug 2020 02:14:51 |
| User entered 'None (0)' | System | 07 Aug 2020 02:14:51 |

US3062128

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-06T21:14:41', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '24b27a25-0488-4afe-8a9a-bdf0466ee196' | System | 07 Aug 2020 02:14:51 |
| User entered 'No (N)' | System | 07 Aug 2020 02:14:51 |

US3062128

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:08

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-06T21:14:49', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '24b27a25-0488-4afe-8a9a-bdf0466ee196' | System | 07 Aug 2020 02:14:51 |
| User entered '06 Aug 2020 21:14' | System | 07 Aug 2020 02:14:51 |

US3062128

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:08

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| User entered '06 Aug 2020 20:33' | System | 06 Aug 2020 22:01:06 |

US3062128

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:08

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| User entered '07 Aug 2020 11:59' | System | 06 Aug 2020 22:01:06 |

US3062128

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| Data entry locked. | System | 06 Aug 2020 22:01:06 |
| User entered 'Day 2' | System | 06 Aug 2020 22:01:06 |

US3062128

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:08

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-07T21:20:32', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'adca88c2-17e2-4f01-bf3b-09d9fc359857' | System | 08 Aug 2020 02:21:24 |
| User entered 'None (0)' | System | 08 Aug 2020 02:21:24 |

US3062128

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:08

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-07T21:20:35', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'adca88c2-17e2-4f01-bf3b-09d9fc359857' | System | 08 Aug 2020 02:21:24 |
| User entered 'None (0)' | System | 08 Aug 2020 02:21:24 |

US3062128

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:08

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-07T21:20:38', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'adca88c2-17e2-4f01-bf3b-09d9fc359857' | System | 08 Aug 2020 02:21:24 |
| User entered 'None (0)' | System | 08 Aug 2020 02:21:24 |

US3062128

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:08

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-07T21:20:41', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'adca88c2-17e2-4f01-bf3b-09d9fc359857' | System | 08 Aug 2020 02:21:24 |
| User entered 'None (0)' | System | 08 Aug 2020 02:21:24 |

US3062128

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:08

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-07T21:20:43', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'adca88c2-17e2-4f01-bf3b-09d9fc359857' | System | 08 Aug 2020 02:21:24 |
| User entered 'None (0)' | System | 08 Aug 2020 02:21:24 |

US3062128

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:08

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-07T21:20:46', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'adca88c2-17e2-4f01-bf3b-09d9fc359857' | System | 08 Aug 2020 02:21:24 |
| User entered 'None (0)' | System | 08 Aug 2020 02:21:24 |

US3062128

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-07T21:20:52', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'adca88c2-17e2-4f01-bf3b-09d9fc359857' | System | 08 Aug 2020 02:21:24 |
| User entered 'No (N)' | System | 08 Aug 2020 02:21:24 |

US3062128

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:08

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-07T21:20:59', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'adca88c2-17e2-4f01-bf3b-09d9fc359857' | System | 08 Aug 2020 02:21:24 |
| User entered '07 Aug 2020 21:20' | System | 08 Aug 2020 02:21:24 |

US3062128

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:08

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| User entered '07 Aug 2020 12:00' | System | 06 Aug 2020 22:01:06 |

US3062128

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:08

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| User entered '08 Aug 2020 11:59' | System | 06 Aug 2020 22:01:06 |

US3062128

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| Data entry locked. | System | 06 Aug 2020 22:01:06 |
| User entered 'Day 3' | System | 06 Aug 2020 22:01:06 |

US3062128

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:08

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-08T21:00:35', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'f97b3e29-76be-46c2-b350-b77ee454473e' | System | 09 Aug 2020 02:01:07 |
| User entered 'None (0)' | System | 09 Aug 2020 02:01:07 |

US3062128

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:08

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-08T21:00:38', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'f97b3e29-76be-46c2-b350-b77ee454473e' | System | 09 Aug 2020 02:01:07 |
| User entered 'None (0)' | System | 09 Aug 2020 02:01:07 |

US3062128

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:08

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-08T21:00:41', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'f97b3e29-76be-46c2-b350-b77ee454473e' | System | 09 Aug 2020 02:01:07 |
| User entered 'None (0)' | System | 09 Aug 2020 02:01:07 |

US3062128

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:08

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-08T21:00:44', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'f97b3e29-76be-46c2-b350-b77ee454473e' | System | 09 Aug 2020 02:01:07 |
| User entered 'None (0)' | System | 09 Aug 2020 02:01:07 |

US3062128

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:08

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-08T21:00:47', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'f97b3e29-76be-46c2-b350-b77ee454473e' | System | 09 Aug 2020 02:01:07 |
| User entered 'None (0)' | System | 09 Aug 2020 02:01:07 |

US3062128

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:08

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-08T21:00:50', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'f97b3e29-76be-46c2-b350-b77ee454473e' | System | 09 Aug 2020 02:01:07 |
| User entered 'None (0)' | System | 09 Aug 2020 02:01:07 |

US3062128

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-08T21:00:53', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'f97b3e29-76be-46c2-b350-b77ee454473e' | System | 09 Aug 2020 02:01:07 |
| User entered 'No (N)' | System | 09 Aug 2020 02:01:07 |

US3062128

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:08

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-08T21:01:00', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'f97b3e29-76be-46c2-b350-b77ee454473e' | System | 09 Aug 2020 02:01:07 |
| User entered '08 Aug 2020 21:01' | System | 09 Aug 2020 02:01:07 |

US3062128

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:08

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| User entered '08 Aug 2020 12:00' | System | 06 Aug 2020 22:01:06 |

US3062128

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:08

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| User entered '09 Aug 2020 11:59' | System | 06 Aug 2020 22:01:06 |

US3062128

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| Data entry locked. | System | 06 Aug 2020 22:01:06 |
| User entered 'Day 4' | System | 06 Aug 2020 22:01:06 |

US3062128

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:08

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-09T21:31:44', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '87606bd9-bca4-4aa9-a7c7-a237454f0147' | System | 10 Aug 2020 02:32:15 |
| User entered 'None (0)' | System | 10 Aug 2020 02:32:15 |

US3062128

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:08

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-09T21:31:47', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '87606bd9-bca4-4aa9-a7c7-a237454f0147' | System | 10 Aug 2020 02:32:15 |
| User entered 'None (0)' | System | 10 Aug 2020 02:32:15 |

US3062128

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:08

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-09T21:31:50', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '87606bd9-bca4-4aa9-a7c7-a237454f0147' | System | 10 Aug 2020 02:32:15 |
| User entered 'None (0)' | System | 10 Aug 2020 02:32:15 |

US3062128

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:08

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-09T21:31:53', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '87606bd9-bca4-4aa9-a7c7-a237454f0147' | System | 10 Aug 2020 02:32:15 |
| User entered 'None (0)' | System | 10 Aug 2020 02:32:15 |

US3062128

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:08

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-09T21:31:57', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '87606bd9-bca4-4aa9-a7c7-a237454f0147' | System | 10 Aug 2020 02:32:15 |
| User entered 'None (0)' | System | 10 Aug 2020 02:32:15 |

US3062128

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:08

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-09T21:31:59', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '87606bd9-bca4-4aa9-a7c7-a237454f0147' | System | 10 Aug 2020 02:32:15 |
| User entered 'None (0)' | System | 10 Aug 2020 02:32:15 |

US3062128

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-09T21:32:05', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '87606bd9-bca4-4aa9-a7c7-a237454f0147' | System | 10 Aug 2020 02:32:15 |
| User entered 'No (N)' | System | 10 Aug 2020 02:32:15 |

US3062128

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:08

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-09T21:32:13', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '87606bd9-bca4-4aa9-a7c7-a237454f0147' | System | 10 Aug 2020 02:32:15 |
| User entered '09 Aug 2020 21:32' | System | 10 Aug 2020 02:32:15 |

US3062128

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:08

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| User entered '09 Aug 2020 12:00' | System | 06 Aug 2020 22:01:06 |

US3062128

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:08

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| User entered '10 Aug 2020 11:59' | System | 06 Aug 2020 22:01:06 |

US3062128

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| Data entry locked. | System | 06 Aug 2020 22:01:06 |
| User entered 'Day 5' | System | 06 Aug 2020 22:01:06 |

US3062128

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:08

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-10T20:47:55', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '826c2c53-e592-4646-8704-89939d8a101b' | System | 11 Aug 2020 01:48:25 |
| User entered 'None (0)' | System | 11 Aug 2020 01:48:25 |

US3062128

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:08

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-10T20:47:59', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '826c2c53-e592-4646-8704-89939d8a101b' | System | 11 Aug 2020 01:48:25 |
| User entered 'None (0)' | System | 11 Aug 2020 01:48:25 |

US3062128

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:08

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-10T20:48:02', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '826c2c53-e592-4646-8704-89939d8a101b' | System | 11 Aug 2020 01:48:25 |
| User entered 'None (0)' | System | 11 Aug 2020 01:48:25 |

US3062128

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:08

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-10T20:48:04', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '826c2c53-e592-4646-8704-89939d8a101b' | System | 11 Aug 2020 01:48:25 |
| User entered 'None (0)' | System | 11 Aug 2020 01:48:25 |

US3062128

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:08

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-10T20:48:08', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '826c2c53-e592-4646-8704-89939d8a101b' | System | 11 Aug 2020 01:48:25 |
| User entered 'None (0)' | System | 11 Aug 2020 01:48:25 |

US3062128

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:08

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-10T20:48:10', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '826c2c53-e592-4646-8704-89939d8a101b' | System | 11 Aug 2020 01:48:25 |
| User entered 'None (0)' | System | 11 Aug 2020 01:48:25 |

US3062128

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-10T20:48:14', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '826c2c53-e592-4646-8704-89939d8a101b' | System | 11 Aug 2020 01:48:25 |
| User entered 'No (N)' | System | 11 Aug 2020 01:48:25 |

US3062128

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:08

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-10T20:48:20', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '826c2c53-e592-4646-8704-89939d8a101b' | System | 11 Aug 2020 01:48:25 |
| User entered '10 Aug 2020 20:48' | System | 11 Aug 2020 01:48:25 |

US3062128

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:08

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| User entered '10 Aug 2020 12:00' | System | 06 Aug 2020 22:01:06 |

US3062128

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:08

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| User entered '11 Aug 2020 11:59' | System | 06 Aug 2020 22:01:06 |

US3062128

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| Data entry locked. | System | 06 Aug 2020 22:01:06 |
| User entered 'Day 6' | System | 06 Aug 2020 22:01:06 |

US3062128

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:08

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-11T21:30:54', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'cc023ea7-faa5-4f3b-977c-0912e889a906' | System | 12 Aug 2020 02:31:26 |
| User entered 'None (0)' | System | 12 Aug 2020 02:31:26 |

US3062128

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:08

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-11T21:30:57', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'cc023ea7-faa5-4f3b-977c-0912e889a906' | System | 12 Aug 2020 02:31:26 |
| User entered 'None (0)' | System | 12 Aug 2020 02:31:26 |

US3062128

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:08

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-11T21:31:00', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'cc023ea7-faa5-4f3b-977c-0912e889a906' | System | 12 Aug 2020 02:31:26 |
| User entered 'None (0)' | System | 12 Aug 2020 02:31:26 |

US3062128

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:08

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-11T21:31:03', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'cc023ea7-faa5-4f3b-977c-0912e889a906' | System | 12 Aug 2020 02:31:26 |
| User entered 'None (0)' | System | 12 Aug 2020 02:31:26 |

US3062128

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:08

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-11T21:31:06', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'cc023ea7-faa5-4f3b-977c-0912e889a906' | System | 12 Aug 2020 02:31:26 |
| User entered 'None (0)' | System | 12 Aug 2020 02:31:26 |

US3062128

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:08

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-11T21:31:08', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'cc023ea7-faa5-4f3b-977c-0912e889a906' | System | 12 Aug 2020 02:31:26 |
| User entered 'None (0)' | System | 12 Aug 2020 02:31:26 |

US3062128

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-11T21:31:11', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'cc023ea7-faa5-4f3b-977c-0912e889a906' | System | 12 Aug 2020 02:31:26 |
| User entered 'No (N)' | System | 12 Aug 2020 02:31:26 |

US3062128

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:08

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-11T21:31:20', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'cc023ea7-faa5-4f3b-977c-0912e889a906' | System | 12 Aug 2020 02:31:26 |
| User entered '11 Aug 2020 21:31' | System | 12 Aug 2020 02:31:26 |

US3062128

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:08

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| User entered '11 Aug 2020 12:00' | System | 06 Aug 2020 22:01:06 |

US3062128

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:08

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| User entered '12 Aug 2020 11:59' | System | 06 Aug 2020 22:01:06 |

US3062128

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| Data entry locked. | System | 06 Aug 2020 22:01:06 |
| User entered 'Day 7' | System | 06 Aug 2020 22:01:06 |

US3062128

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:08

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-12T21:10:32', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '5df3027b-aec6-47c2-acf9-6813ab323de6' | System | 13 Aug 2020 02:11:00 |
| User entered 'None (0)' | System | 13 Aug 2020 02:11:00 |

US3062128

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:08

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-12T21:10:34', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '5df3027b-aec6-47c2-acf9-6813ab323de6' | System | 13 Aug 2020 02:11:00 |
| User entered 'None (0)' | System | 13 Aug 2020 02:11:00 |

US3062128

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:08

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-12T21:10:37', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '5df3027b-aec6-47c2-acf9-6813ab323de6' | System | 13 Aug 2020 02:11:00 |
| User entered 'None (0)' | System | 13 Aug 2020 02:11:00 |

US3062128

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:08

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-12T21:10:40', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '5df3027b-aec6-47c2-acf9-6813ab323de6' | System | 13 Aug 2020 02:11:00 |
| User entered 'None (0)' | System | 13 Aug 2020 02:11:00 |

US3062128

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:08

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-12T21:10:42', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '5df3027b-aec6-47c2-acf9-6813ab323de6' | System | 13 Aug 2020 02:11:00 |
| User entered 'None (0)' | System | 13 Aug 2020 02:11:00 |

US3062128

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:08

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-12T21:10:44', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '5df3027b-aec6-47c2-acf9-6813ab323de6' | System | 13 Aug 2020 02:11:00 |
| User entered 'None (0)' | System | 13 Aug 2020 02:11:00 |

US3062128

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-12T21:10:47', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '5df3027b-aec6-47c2-acf9-6813ab323de6' | System | 13 Aug 2020 02:11:00 |
| User entered 'No (N)' | System | 13 Aug 2020 02:11:00 |

US3062128

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:08

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-08-12T21:10:54', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '5df3027b-aec6-47c2-acf9-6813ab323de6' | System | 13 Aug 2020 02:11:00 |
| User entered '12 Aug 2020 21:10' | System | 13 Aug 2020 02:11:00 |

US3062128

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:08

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| User entered '12 Aug 2020 12:00' | System | 06 Aug 2020 22:01:06 |

US3062128

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:08

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| User entered '13 Aug 2020 11:59' | System | 06 Aug 2020 22:01:06 |

US3062128

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:08

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Sep 2020 16:59:29 |
| User entered 'Yes (Y)' | Janna Martinez (b) (4) | 14 Aug 2020 19:08:30 |
| | (b) (4) | |

US3062128

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:08

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Sep 2020 16:59:29 |
| User entered '13 Aug 2020' | Janna Martinez (b) (4) | 14 Aug 2020 19:08:30 |

US3062128

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:08

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Sep 2020 16:59:29 |
| User entered 'Contact Made (CONTACT MADE)' | Janna Martinez (b) (4) | 14 Aug 2020 19:08:30 |

US3062128

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:08

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Sep 2020 16:59:29 |
| User entered empty. | Janna Martinez (b) (4) | 14 Aug 2020 19:08:30 |
| | (b) (4) | |

US3062128

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:08

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Sep 2020 16:59:48 |
| User entered 'Yes (Y)' | Janna Martinez (b) (4) | 14 Aug 2020 19:08:17 |
| | (b) (4) | |

US3062128

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:08

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User entered 'I' | System | 14 Aug 2020 19:08:17 |

US3062128

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:08

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Sep 2020 21:29:22 |
| User entered 'Yes (Y)' | Janna Martinez (b) (4) | 21 Aug 2020 13:39:56 |
| | (b) (4) | |

US3062128

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:08

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Sep 2020 21:29:22 |
| User entered '20 Aug 2020' | Janna Martinez (b) (4) | 21 Aug 2020 13:39:56 |
| | (b) (4) | |

US3062128

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:08

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Sep 2020 21:29:22 |
| User entered 'Contact Made (CONTACT MADE)' | Janna Martinez (b) (4) | 21 Aug 2020 13:39:56 |
| | (b) (4) | |

US3062128

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:08

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Sep 2020 21:29:22 |
| User entered empty. | Janna Martinez (b) (4) | 21 Aug 2020 13:39:56 |
| | (b) (4) | |

US3062128

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:08

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Sep 2020 21:29:25 |
| User entered 'Yes (Y)' | Janna Martinez (b) (4) | 21 Aug 2020 13:40:05 |
| | (b) (4) | |

US3062128

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:08

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User entered 'I' | System | 21 Aug 2020 13:40:05 |

US3062128

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:08

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:43:52 |
| User entered 'Yes (Y)' | Janna Martinez (b) (4) | 29 Aug 2020 23:02:39 |
| | (b) (4) | |

US3062128

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:08

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:43:52 |
| User entered '28 Aug 2020' | Janna Martinez (b) (4) | 29 Aug 2020 23:02:39 |
| | (b) (4) | |

US3062128

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:08

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:43:52 |
| User entered 'Contact Made (CONTACT MADE)' | Janna Martinez (b) (4) | 29 Aug 2020 23:02:39 |
| | (b) (4) | |

US3062128

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:08

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:43:52 |
| User entered empty. | Janna Martinez (b) (4) | 29 Aug 2020 23:02:39 |
| | (b) (4) | |

US3062128

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:08

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:43:55 |
| User entered 'Yes (Y)' | Janna Martinez (b) (4) | 29 Aug 2020 23:02:41 |
| | (b) (4) | |

US3062128

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:08

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User entered 'I' | System | 29 Aug 2020 23:02:41 |

US3062128

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:03:08

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:48 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:44:54 |
| User entered 'Yes (Y)' | Sherry Henning (b) (4) | 03 Sep 2020 17:23:19 |
| | (b) (4) | |

US3062128

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:48 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:44:54 |
| User entered '3 Sep 2020' | Sherry Henning (b) (4) | 03 Sep 2020 17:23:19 |
| | (b) (4) | |

US3062128

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|--------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:48 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:44:54 |
| User entered 'Clinic (Clinic)' | Sherry Henning (b) (4) | 03 Sep 2020 17:23:19 |
| | (b) (4) | |

US3062128

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:03:08

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User entered 'VISIT2' | System | 03 Sep 2020 17:23:19 |

US3062128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:08

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User accepted default value 'Pre-Dose (PREDOSE)' | Janna Martinez (b) (4) | 03 Sep 2020 21:51:03 |
| | (b) (4) | |

US3062128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:08

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:48 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:48:04 |
| User entered 'Yes (Y)' | Janna Martinez (b) (4) | 03 Sep 2020 21:51:03 |
| | (b) (4) | |

US3062128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:08

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:48 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:48:06 |
| User entered '03 Sep 2020' | Janna Martinez (b) (4) | 03 Sep 2020 21:51:03 |
| | (b) (4) | |

US3062128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:48 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:48:07 |
| User entered '11:14' | Janna Martinez (b) (4) | 03 Sep 2020 21:51:03 |
| | (b) (4) | |

US3062128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User entered '03 Sep 2020 11:14' | System | 03 Sep 2020 21:51:03 |

US3062128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:08

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:48 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:48:09 |
| User entered '98.0' F | Janna Martinez (b) (4) | 03 Sep 2020 21:51:03 |
| | (b) (4) | |

US3062128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:08

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:48 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:48:11 |
| User entered 'Oral (Oral)' | Janna Martinez (b) (4) | 03 Sep 2020 21:51:03 |
| | (b) (4) | |

US3062128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:08

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:48 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:48:15 |
| User entered empty. | Janna Martinez (b) (4) | 03 Sep 2020 21:51:03 |
| | (b) (4) | |

US3062128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:08

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:48 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:51:13 |
| User entered '67' | Janna Martinez (b) (4) | 03 Sep 2020 21:51:03 |
| | (b) (4) | |

US3062128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:08

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User entered 'bpm' | System | 03 Sep 2020 21:51:03 |

US3062128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:48 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:51:12 |
| User entered '16' | Janna Martinez (b) (4) | 03 Sep 2020 21:51:03 |
| | (b) (4) | |

US3062128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:08

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User entered 'breaths/min' | System | 03 Sep 2020 21:51:03 |

US3062128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:08

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:48 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:51:08 |
| User entered '119' | Janna Martinez (b) (4) | 03 Sep 2020 21:51:03 |
| | (b) (4) | |

US3062128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:08

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User entered 'mmHg' | System | 03 Sep 2020 21:51:03 |

US3062128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:08

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:48 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:51:10 |
| User entered '75' | Janna Martinez (b) (4) | 03 Sep 2020 21:51:03 |
| | (b) (4) | |

US3062128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:08

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User entered 'mmHg' | System | 03 Sep 2020 21:51:03 |

US3062128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:08

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User accepted default value 'Post-Dose (POSTDOSE)' | Janna Martinez (b) (4) | 03 Sep 2020 21:52:01 |
| | (b) (4) | |

US3062128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:08

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:48 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:47:42 |
| User entered 'Yes (Y)' | Janna Martinez (b) (4) | 03 Sep 2020 21:52:01 |
| | (b) (4) | |

US3062128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:08

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:48 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:47:44 |
| User entered '03 Sep 2020' | Janna Martinez (b) (4) | 03 Sep 2020 21:52:01 |
| | (b) (4) | |

US3062128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:48 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:47:45 |
| User entered '12:56' | Janna Martinez (b) (4) | 03 Sep 2020 21:52:01 |
| | (b) (4) | |

US3062128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User entered '03 Sep 2020 12:56' | System | 03 Sep 2020 21:52:01 |

US3062128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:08

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:48 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:47:46 |
| User entered '98.3' F | Janna Martinez (b) (4) | 03 Sep 2020 21:52:01 |
| | (b) (4) | |

US3062128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:08

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:48 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:47:49 |
| User entered 'Oral (Oral)' | Janna Martinez (b) (4) | 03 Sep 2020 21:52:01 |
| | (b) (4) | |

US3062128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:08

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:48 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:47:48 |
| User entered empty. | Janna Martinez (b) (4) | 03 Sep 2020 21:52:01 |
| | (b) (4) | |

US3062128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:08

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:48 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Oct 2020 15:17:32 |
| User closed query 'Per source pulse collected at 12:56 is 70 B/M. Please verify and update if needed. ' (Site from CRA). | (b) (4), (b) (6) | 08 Oct 2020 15:17:30 |
| Query 'Per source pulse collected at 12:56 is 70 B/M. Please verify and update if needed. ' answered with 'updated' (Site from CRA). | marissa Mueller (b) (4) | 07 Oct 2020 23:05:12 |
| User entered '70' reason for change: Data Entry Error | (b) (4) | |
| | marissa Mueller (b) (4) | 07 Oct 2020 23:05:06 |
| | (b) (4) | |
| User opened query 'Per source pulse collected at 12:56 is 70 B/M. Please verify and update if needed. ' (Site from CRA). | (b) (4), (b) (6) | 07 Oct 2020 14:47:38 |
| User entered '68' | Janna Martinez (b) (4) | 03 Sep 2020 21:52:01 |
| | (b) (4) | |

US3062128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:08

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User entered 'bpm' | System | 03 Sep 2020 21:52:01 |

US3062128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:48 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:47:55 |
| User entered '16' | Janna Martinez (b) (4) | 03 Sep 2020 21:52:01 |
| | (b) (4) | |

US3062128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:08

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User entered 'breaths/min' | System | 03 Sep 2020 21:52:01 |

US3062128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:08

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:48 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:47:53 |
| User entered '135' | Janna Martinez (b) (4) | 03 Sep 2020 21:52:01 |
| | (b) (4) | |

US3062128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:08

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User entered 'mmHg' | System | 03 Sep 2020 21:52:01 |

US3062128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:08

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:48 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:47:57 |
| User entered '73' | Janna Martinez (b) (4) | 03 Sep 2020 21:52:01 |
| | (b) (4) | |

US3062128

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:08

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User entered 'mmHg' | System | 03 Sep 2020 21:52:01 |

US3062128

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:03:08

Was the physical examination performed?

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:48 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:51:38 |
| User entered 'Yes (Y)' | Janna Martinez (b) (4) | 03 Sep 2020 21:52:18 |
| | (b) (4) | |

US3062128

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:03:08

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:48 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:51:38 |
| User entered '03 Sep 2020' | Janna Martinez (b) (4) | 03 Sep 2020 21:52:18 |
| | (b) (4) | |

US3062128

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:03:08

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:48 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:45:47 |
| User entered 'Yes (Y)' | Sherry Henning (b) (4) | 03 Sep 2020 17:24:02 |
| | (b) (4) | |

US3062128

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:03:08

If No, reason not given

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:48 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:45:47 |
| User entered empty. | Sherry Henning (b) (4) | 03 Sep 2020 17:24:02 |
| | (b) (4) | |

US3062128

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:03:08

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) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:48 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:45:47 |
| User entered empty. | Sherry Henning (b) (4) | 03 Sep 2020 17:24:02 |

US3062128

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:03:08

[What was the study treatment?](#)

| Audit | User | Time (GMT) |
|-------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User entered 'MRNA-1273 OR PLACEBO' | System | 03 Sep 2020 17:24:02 |

US3062128

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:03:08

What was the treatment date? (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:48 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:45:47 |
| User entered '3 Sep 2020' | Sherry Henning (b) (4) | 03 Sep 2020 17:24:02 |

US3062128

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:48 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:45:47 |
| User entered '12:15' | Sherry Henning (b) (4) | 03 Sep 2020 17:24:02 |

US3062128

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User entered '3 Sep 2020 12:15' | System | 03 Sep 2020 17:24:02 |

US3062128

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:03:08

Which arm was used to give treatment?

| Audit | User | Time (GMT) |
|------------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:48 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:45:47 |
| User entered 'Left Arm (LEFT ARM)' | Sherry Henning (b) (4) | 03 Sep 2020 17:24:02 |
| | (b) (4) | |

US3062128

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:45:47 |
| User entered 'ONCE' | System | 03 Sep 2020 17:24:02 |

US3062128

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:03:08

What was the route of administration for the study treatment?

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User entered 'INTRAMUSCULAR' | System | 03 Sep 2020 17:24:02 |

US3062128

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:03:08

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:48 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:45:26 |
| User entered 'Yes (Y)' | Janna Martinez (b) (4) | 03 Sep 2020 21:52:39 |
| | (b) (4) | |

US3062128

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:03:08

Collection date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:48 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:45:26 |
| User entered '03 Sep 2020' | Janna Martinez (b) (4) | 03 Sep 2020 21:52:39 |
| | (b) (4) | |

US3062128

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:03:08

Collection time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:48 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:45:26 |
| User entered '11:37' | Janna Martinez (b) (4) | 03 Sep 2020 21:52:39 |
| | (b) (4) | |

US3062128

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:03:08

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User entered '03 Sep 2020 11:37' | System | 03 Sep 2020 21:52:39 |

US3062128

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:03:08

Collection date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:48 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:45:32 |
| User entered '03 Sep 2020' | Janna Martinez (b) (4) | 03 Sep 2020 21:52:53 |
| | (b) (4) | |

US3062128

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:03:08

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | Janna Martinez (b) (4) | 03 Sep 2020 21:52:53 |
| | (b) (4) | |

US3062128

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:03:08

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:48 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:45:32 |
| User entered 'Yes (Y)' | Janna Martinez (b) (4) | 03 Sep 2020 21:52:53 |
| | (b) (4) | |

US3062128

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:03:08

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:48 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:45:32 |
| User entered '11:32' | Janna Martinez (b) (4) | 03 Sep 2020 21:52:53 |
| | (b) (4) | |

US3062128

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:03:08

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User entered '03 Sep 2020 11:32' | System | 03 Sep 2020 21:52:53 |

US3062128

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:03:08

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | Janna Martinez (b) (4) | 03 Sep 2020 21:52:53 |
| | (b) (4) | |

US3062128

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:03:08

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:48 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:45:32 |
| User entered 'No (N)' | Janna Martinez (b) (4) | 03 Sep 2020 21:52:53 |
| | (b) (4) | |

US3062128

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:03:08

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:48 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:45:32 |
| User entered empty. | Janna Martinez (b) (4) | 03 Sep 2020 21:52:53 |
| | (b) (4) | |

US3062128

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:03:08

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User entered empty. | System | 03 Sep 2020 21:52:53 |

US3062128

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:08

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:48 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:51:40 |
| User entered 'Yes (Y)' | Janna Martinez (b) (4) | 03 Sep 2020 21:52:58 |
| | (b) (4) | |

US3062128

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:08

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User entered 'I' | System | 03 Sep 2020 21:52:58 |

US3062128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| Data entry locked. | System | 03 Sep 2020 17:24:02 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 03 Sep 2020 17:24:02 |

US3062128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:03:08

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-03T12:51:00', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'a81a8a4a-eeff-4029-beaa-97baadcc17a9' | System | 03 Sep 2020 17:51:30 |
| User entered 'Yes (Y)' | System | 03 Sep 2020 17:51:30 |

US3062128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:03:08

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-03T12:51:17', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'a81a8a4a-eeff-4029-beaa-97baadcc17a9' | System | 03 Sep 2020 17:51:30 |
| User entered '98.3' | System | 03 Sep 2020 17:51:30 |

US3062128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-03T12:51:22', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'a81a8a4a-eeff-4029-beaa-97baadcc17a9' | System | 03 Sep 2020 17:51:30 |
| User entered 'No (N)' | System | 03 Sep 2020 17:51:30 |

US3062128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:03:08

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-03T12:51:27', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'a81a8a4a-eeff-4029-beaa-97baadcc17a9' | System | 03 Sep 2020 17:51:30 |
| User entered '03 Sep 2020 12:51' | System | 03 Sep 2020 17:51:30 |

US3062128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:03:08

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| User entered '03 Sep 2020 12:35' | System | 03 Sep 2020 17:24:02 |

US3062128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:03:08

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| User entered '03 Sep 2020 15:05' | System | 03 Sep 2020 17:24:02 |

US3062128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| Data entry locked. | System | 03 Sep 2020 17:24:02 |
| User entered 'Day 1, after vaccination (at home)' | System | 03 Sep 2020 17:24:02 |

US3062128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:03:08

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-03T21:26:12', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'a3be5903-92f2-43ff-b482-713be5be0c27' | System | 04 Sep 2020 02:26:30 |
| User entered 'Yes (Y)' | System | 04 Sep 2020 02:26:30 |

US3062128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:03:08

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-03T21:26:18', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'a3be5903-92f2-43ff-b482-713be5be0c27' | System | 04 Sep 2020 02:26:30 |
| User entered '97.9' | System | 04 Sep 2020 02:26:30 |

US3062128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-03T21:26:22', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'a3be5903-92f2-43ff-b482-713be5be0c27' | System | 04 Sep 2020 02:26:30 |
| User entered 'No (N)' | System | 04 Sep 2020 02:26:30 |

US3062128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:03:08

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-03T21:26:27', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'a3be5903-92f2-43ff-b482-713be5be0c27' | System | 04 Sep 2020 02:26:30 |
| User entered '03 Sep 2020 21:26' | System | 04 Sep 2020 02:26:30 |

US3062128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:03:08

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| User entered '03 Sep 2020 16:00' | System | 03 Sep 2020 17:24:02 |

US3062128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:03:08

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| User entered '04 Sep 2020 11:59' | System | 03 Sep 2020 17:24:02 |

US3062128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| Data entry locked. | System | 03 Sep 2020 17:24:02 |
| User entered 'Day 2' | System | 03 Sep 2020 17:24:02 |

US3062128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:03:08

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-04T21:14:43', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '3327db77-b610-428d-9720-6f50bd65ddcb' | System | 05 Sep 2020 02:15:07 |
| User entered 'Yes (Y)' | System | 05 Sep 2020 02:15:07 |

US3062128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:03:08

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-04T21:14:52', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '3327db77-b610-428d-9720-6f50bd65ddcb' User entered '97.5' | System | 05 Sep 2020 02:15:07 |
| | System | 05 Sep 2020 02:15:07 |

US3062128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-04T21:14:56', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '3327db77-b610-428d-9720-6f50bd65ddcb' | System | 05 Sep 2020 02:15:07 |
| User entered 'No (N)' | System | 05 Sep 2020 02:15:07 |

US3062128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:03:08

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-04T21:15:00', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '3327db77-b610-428d-9720-6f50bd65ddcb' | System | 05 Sep 2020 02:15:07 |
| User entered '04 Sep 2020 21:15' | System | 05 Sep 2020 02:15:07 |

US3062128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:03:08

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| User entered '04 Sep 2020 12:00' | System | 03 Sep 2020 17:24:02 |

US3062128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:03:08

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| User entered '05 Sep 2020 11:59' | System | 03 Sep 2020 17:24:02 |

US3062128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| Data entry locked. | System | 03 Sep 2020 17:24:02 |
| User entered 'Day 3' | System | 03 Sep 2020 17:24:02 |

US3062128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:03:08

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-05T20:56:58', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '29ebef54-a579-4f2d-bc05-b11cfd2fc6be' | System | 06 Sep 2020 01:57:18 |
| User entered 'Yes (Y)' | System | 06 Sep 2020 01:57:18 |

US3062128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:03:08

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-05T20:57:07', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '29ebef54-a579-4f2d-bc05-b11cfd2fc6be' | System | 06 Sep 2020 01:57:18 |
| User entered '96.6' | System | 06 Sep 2020 01:57:18 |

US3062128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-05T20:57:10', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '29ebef54-a579-4f2d-bc05-b11cfd2fc6be' | System | 06 Sep 2020 01:57:18 |
| User entered 'No (N)' | System | 06 Sep 2020 01:57:18 |

US3062128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:03:08

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-05T20:57:15', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '29ebef54-a579-4f2d-bc05-b11cfd2fc6be' | System | 06 Sep 2020 01:57:18 |
| User entered '05 Sep 2020 20:57' | System | 06 Sep 2020 01:57:18 |

US3062128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:03:08

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| User entered '05 Sep 2020 12:00' | System | 03 Sep 2020 17:24:02 |

US3062128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:03:08

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| User entered '06 Sep 2020 11:59' | System | 03 Sep 2020 17:24:02 |

US3062128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| Data entry locked. | System | 03 Sep 2020 17:24:02 |
| User entered 'Day 4' | System | 03 Sep 2020 17:24:02 |

US3062128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:03:08

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-06T21:37:25', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '24eee4aa-4bc4-49e1-9948-b4b215f56ce0' | System | 07 Sep 2020 02:37:54 |
| User entered 'Yes (Y)' | System | 07 Sep 2020 02:37:54 |

US3062128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:03:08

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-06T21:37:36', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '24eee4aa-4bc4-49e1-9948-b4b215f56ce0' | System | 07 Sep 2020 02:37:54 |
| User entered '97.1' | System | 07 Sep 2020 02:37:54 |

US3062128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-06T21:37:44', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '24eee4aa-4bc4-49e1-9948-b4b215f56ce0' | System | 07 Sep 2020 02:37:54 |
| User entered 'No (N)' | System | 07 Sep 2020 02:37:54 |

US3062128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:03:08

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-06T21:37:49', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '24eee4aa-4bc4-49e1-9948-b4b215f56ce0' | System | 07 Sep 2020 02:37:54 |
| User entered '06 Sep 2020 21:37' | System | 07 Sep 2020 02:37:54 |

US3062128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:03:08

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| User entered '06 Sep 2020 12:00' | System | 03 Sep 2020 17:24:02 |

US3062128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:03:08

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| User entered '07 Sep 2020 11:59' | System | 03 Sep 2020 17:24:02 |

US3062128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| Data entry locked. | System | 03 Sep 2020 17:24:02 |
| User entered 'Day 5' | System | 03 Sep 2020 17:24:02 |

US3062128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:03:08

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-07T21:15:35', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'f2ebad8b-1f96-4058-8053-ef5e7a7d7dcb' | System | 08 Sep 2020 02:16:03 |
| User entered 'Yes (Y)' | System | 08 Sep 2020 02:16:03 |

US3062128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:03:08

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-07T21:15:50', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'f2ebad8b-1f96-4058-8053-ef5e7a7d7dcb' | System | 08 Sep 2020 02:16:03 |
| User entered '96.4' | System | 08 Sep 2020 02:16:03 |

US3062128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-07T21:15:54', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'f2ebad8b-1f96-4058-8053-ef5e7a7d7dcb' | System | 08 Sep 2020 02:16:03 |
| User entered 'No (N)' | System | 08 Sep 2020 02:16:03 |

US3062128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:03:08

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-07T21:15:59', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'f2ebad8b-1f96-4058-8053-ef5e7a7d7dcb' | System | 08 Sep 2020 02:16:03 |
| User entered '07 Sep 2020 21:15' | System | 08 Sep 2020 02:16:03 |

US3062128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:03:08

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| User entered '07 Sep 2020 12:00' | System | 03 Sep 2020 17:24:02 |

US3062128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:03:08

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| User entered '08 Sep 2020 11:59' | System | 03 Sep 2020 17:24:02 |

US3062128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| Data entry locked. | System | 03 Sep 2020 17:24:02 |
| User entered 'Day 6' | System | 03 Sep 2020 17:24:02 |

US3062128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:03:08

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-08T21:39:00', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '977db419-f99c-46a2-9292-9441564ee756' | System | 09 Sep 2020 02:39:17 |
| User entered 'Yes (Y)' | System | 09 Sep 2020 02:39:17 |

US3062128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:03:08

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-08T21:39:07', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '977db419-f99c-46a2-9292-9441564ee756' | System | 09 Sep 2020 02:39:17 |
| User entered '95.9' | System | 09 Sep 2020 02:39:17 |

US3062128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-08T21:39:11', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '977db419-f99c-46a2-9292-9441564ee756' | System | 09 Sep 2020 02:39:17 |
| User entered 'No (N)' | System | 09 Sep 2020 02:39:17 |

US3062128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:03:08

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-08T21:39:15', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '977db419-f99c-46a2-9292-9441564ee756' | System | 09 Sep 2020 02:39:17 |
| User entered '08 Sep 2020 21:39' | System | 09 Sep 2020 02:39:17 |

US3062128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:03:08

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| User entered '08 Sep 2020 12:00' | System | 03 Sep 2020 17:24:02 |

US3062128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:03:08

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| User entered '09 Sep 2020 11:59' | System | 03 Sep 2020 17:24:02 |

US3062128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| Data entry locked. | System | 03 Sep 2020 17:24:02 |
| User entered 'Day 7' | System | 03 Sep 2020 17:24:02 |

US3062128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:03:08

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-09T21:40:10', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'ca534ba2-bf4b-4a58-b0a0-d5aae4617d64' | System | 10 Sep 2020 02:41:11 |
| User entered 'Yes (Y)' | System | 10 Sep 2020 02:41:11 |

US3062128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:03:08

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-09T21:41:00', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'ca534ba2-bf4b-4a58-b0a0-d5aae4617d64' | System | 10 Sep 2020 02:41:11 |
| User entered '97.6' | System | 10 Sep 2020 02:41:11 |

US3062128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-09T21:41:04', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'ca534ba2-bf4b-4a58-b0a0-d5aae4617d64' | System | 10 Sep 2020 02:41:11 |
| User entered 'No (N)' | System | 10 Sep 2020 02:41:11 |

US3062128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:03:08

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-09T21:41:08', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'ca534ba2-bf4b-4a58-b0a0-d5aae4617d64' | System | 10 Sep 2020 02:41:11 |
| User entered '09 Sep 2020 21:41' | System | 10 Sep 2020 02:41:11 |

US3062128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:03:08

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| User entered '09 Sep 2020 12:00' | System | 03 Sep 2020 17:24:02 |

US3062128

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:03:08

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| User entered '10 Sep 2020 11:59' | System | 03 Sep 2020 17:24:02 |

US3062128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| Data entry locked. | System | 03 Sep 2020 17:24:02 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 03 Sep 2020 17:24:02 |

US3062128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:03:08

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-03T12:51:34', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '1eb01806-94fe-4ae4-aec9-92d8aa98c29a' | System | 03 Sep 2020 17:51:58 |
| User entered 'None (1)' | System | 03 Sep 2020 17:51:58 |

US3062128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-03T12:51:42', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '1eb01806-94fe-4ae4-aec9-92d8aa98c29a' | System | 03 Sep 2020 17:51:58 |
| User entered 'No (N)' | System | 03 Sep 2020 17:51:58 |

US3062128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-03T12:51:45', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '1eb01806-94fe-4ae4-aec9-92d8aa98c29a' | System | 03 Sep 2020 17:51:58 |
| User entered 'No (N)' | System | 03 Sep 2020 17:51:58 |

US3062128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:03:08

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-03T12:51:49', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '1eb01806-94fe-4ae4-aec9-92d8aa98c29a' | System | 03 Sep 2020 17:51:58 |
| User entered 'None (1)' | System | 03 Sep 2020 17:51:58 |

US3062128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:03:08

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-03T12:51:56', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '1eb01806-94fe-4ae4-aec9-92d8aa98c29a' | System | 03 Sep 2020 17:51:58 |
| User entered '03 Sep 2020 12:51' | System | 03 Sep 2020 17:51:58 |

US3062128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:03:08

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| User entered '03 Sep 2020 12:35' | System | 03 Sep 2020 17:24:02 |

US3062128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:03:08

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| User entered '03 Sep 2020 15:05' | System | 03 Sep 2020 17:24:02 |

US3062128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| Data entry locked. | System | 03 Sep 2020 17:24:02 |
| User entered 'Day 1, after vaccination (at home)' | System | 03 Sep 2020 17:24:02 |

US3062128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:03:08

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-03T21:26:44', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'c727c46d-400e-4621-a445-3c946e3c6ae4' | System | 04 Sep 2020 02:27:01 |
| User entered 'None (1)' | System | 04 Sep 2020 02:27:01 |

US3062128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:03:08

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-03T21:26:47', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'c727c46d-400e-4621-a445-3c946e3c6ae4' | System | 04 Sep 2020 02:27:01 |
| User entered 'No (N)' | System | 04 Sep 2020 02:27:01 |

US3062128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-03T21:26:50', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'c727c46d-400e-4621-a445-3c946e3c6ae4' | System | 04 Sep 2020 02:27:01 |
| User entered 'No (N)' | System | 04 Sep 2020 02:27:01 |

US3062128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:03:08

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-03T21:26:53', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'c727c46d-400e-4621-a445-3c946e3c6ae4' | System | 04 Sep 2020 02:27:01 |
| User entered 'None (1)' | System | 04 Sep 2020 02:27:01 |

US3062128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:03:08

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-03T21:26:58', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'c727c46d-400e-4621-a445-3c946e3c6ae4' | System | 04 Sep 2020 02:27:01 |
| User entered '03 Sep 2020 21:26' | System | 04 Sep 2020 02:27:01 |

US3062128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:03:08

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| User entered '03 Sep 2020 16:00' | System | 03 Sep 2020 17:24:02 |

US3062128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:03:08

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| User entered '04 Sep 2020 11:59' | System | 03 Sep 2020 17:24:02 |

US3062128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| Data entry locked. | System | 03 Sep 2020 17:24:02 |
| User entered 'Day 2' | System | 03 Sep 2020 17:24:02 |

US3062128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:03:08

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-04T21:15:07', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '4302cee0-db48-41e0-906b-d55812418aea' | System | 05 Sep 2020 02:15:29 |
| User entered 'None (1)' | System | 05 Sep 2020 02:15:29 |

US3062128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:03:08

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-04T21:15:13', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '4302cee0-db48-41e0-906b-d55812418aea' | System | 05 Sep 2020 02:15:29 |
| User entered 'No (N)' | System | 05 Sep 2020 02:15:29 |

US3062128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-04T21:15:17', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '4302cee0-db48-41e0-906b-d55812418aea' | System | 05 Sep 2020 02:15:29 |
| User entered 'No (N)' | System | 05 Sep 2020 02:15:29 |

US3062128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:03:08

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-04T21:15:20', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '4302cee0-db48-41e0-906b-d55812418aea' | System | 05 Sep 2020 02:15:29 |
| User entered 'None (1)' | System | 05 Sep 2020 02:15:29 |

US3062128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:03:08

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-04T21:15:25', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '4302cee0-db48-41e0-906b-d55812418aea' | System | 05 Sep 2020 02:15:29 |
| User entered '04 Sep 2020 21:15' | System | 05 Sep 2020 02:15:29 |

US3062128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:03:08

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| User entered '04 Sep 2020 12:00' | System | 03 Sep 2020 17:24:02 |

US3062128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:03:08

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| User entered '05 Sep 2020 11:59' | System | 03 Sep 2020 17:24:02 |

US3062128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| Data entry locked. | System | 03 Sep 2020 17:24:02 |
| User entered 'Day 3' | System | 03 Sep 2020 17:24:02 |

US3062128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:03:08

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-05T20:57:19', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'bb4403db-2d72-49e2-b2df-ace5a2186745' | System | 06 Sep 2020 01:57:46 |
| User entered 'None (1)' | System | 06 Sep 2020 01:57:46 |

US3062128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:03:08

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-05T20:57:30', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'bb4403db-2d72-49e2-b2df-ace5a2186745' | System | 06 Sep 2020 01:57:46 |
| User entered 'No (N)' | System | 06 Sep 2020 01:57:46 |

US3062128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-05T20:57:33', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'bb4403db-2d72-49e2-b2df-ace5a2186745' | System | 06 Sep 2020 01:57:46 |
| User entered 'No (N)' | System | 06 Sep 2020 01:57:46 |

US3062128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:03:08

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-05T20:57:35', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'bb4403db-2d72-49e2-b2df-ace5a2186745' | System | 06 Sep 2020 01:57:46 |
| User entered 'None (1)' | System | 06 Sep 2020 01:57:46 |

US3062128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:03:08

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-05T20:57:41', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'bb4403db-2d72-49e2-b2df-ace5a2186745' | System | 06 Sep 2020 01:57:46 |
| User entered '05 Sep 2020 20:57' | System | 06 Sep 2020 01:57:46 |

US3062128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:03:08

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| User entered '05 Sep 2020 12:00' | System | 03 Sep 2020 17:24:02 |

US3062128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:03:08

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| User entered '06 Sep 2020 11:59' | System | 03 Sep 2020 17:24:02 |

US3062128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| Data entry locked. | System | 03 Sep 2020 17:24:02 |
| User entered 'Day 4' | System | 03 Sep 2020 17:24:02 |

US3062128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:03:08

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-06T21:37:55', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'c00bf076-38c2-4b04-b753-01921e810dac' | System | 07 Sep 2020 02:38:16 |
| User entered 'None (1)' | System | 07 Sep 2020 02:38:16 |

US3062128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-06T21:37:59', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'c00bf076-38c2-4b04-b753-01921e810dac' | System | 07 Sep 2020 02:38:16 |
| User entered 'No (N)' | System | 07 Sep 2020 02:38:16 |

US3062128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-06T21:38:02', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'c00bf076-38c2-4b04-b753-01921e810dac' | System | 07 Sep 2020 02:38:16 |
| User entered 'No (N)' | System | 07 Sep 2020 02:38:16 |

US3062128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:03:08

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-06T21:38:05', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'c00bf076-38c2-4b04-b753-01921e810dac' | System | 07 Sep 2020 02:38:16 |
| User entered 'None (1)' | System | 07 Sep 2020 02:38:16 |

US3062128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:03:08

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-06T21:38:14', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'c00bf076-38c2-4b04-b753-01921e810dac' | System | 07 Sep 2020 02:38:16 |
| User entered '06 Sep 2020 21:38' | System | 07 Sep 2020 02:38:16 |

US3062128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:03:08

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| User entered '06 Sep 2020 12:00' | System | 03 Sep 2020 17:24:02 |

US3062128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:03:08

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| User entered '07 Sep 2020 11:59' | System | 03 Sep 2020 17:24:02 |

US3062128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| Data entry locked. | System | 03 Sep 2020 17:24:02 |
| User entered 'Day 5' | System | 03 Sep 2020 17:24:02 |

US3062128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:03:08

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-07T21:16:04', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'ddcb2ac3-4c36-4f7b-95fb-e7d203c2ba08' | System | 08 Sep 2020 02:16:27 |
| User entered 'None (1)' | System | 08 Sep 2020 02:16:27 |

US3062128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-07T21:16:12', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'ddcb2ac3-4c36-4f7b-95fb-e7d203c2ba08' | System | 08 Sep 2020 02:16:27 |
| User entered 'No (N)' | System | 08 Sep 2020 02:16:27 |

US3062128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-07T21:16:15', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'ddcb2ac3-4c36-4f7b-95fb-e7d203c2ba08' | System | 08 Sep 2020 02:16:27 |
| User entered 'No (N)' | System | 08 Sep 2020 02:16:27 |

US3062128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:03:08

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-07T21:16:18', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'ddcb2ac3-4c36-4f7b-95fb-e7d203c2ba08' | System | 08 Sep 2020 02:16:27 |
| User entered 'None (1)' | System | 08 Sep 2020 02:16:27 |

US3062128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:03:08

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-07T21:16:24', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'ddcb2ac3-4c36-4f7b-95fb-e7d203c2ba08' | System | 08 Sep 2020 02:16:27 |
| User entered '07 Sep 2020 21:16' | System | 08 Sep 2020 02:16:27 |

US3062128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:03:08

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| User entered '07 Sep 2020 12:00' | System | 03 Sep 2020 17:24:02 |

US3062128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:03:08

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| User entered '08 Sep 2020 11:59' | System | 03 Sep 2020 17:24:02 |

US3062128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| Data entry locked. | System | 03 Sep 2020 17:24:02 |
| User entered 'Day 6' | System | 03 Sep 2020 17:24:02 |

US3062128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:03:08

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

Please select one response below

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-08T21:39:21', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '66cf3830-6047-46d6-9914-3ed12214256' | System | 09 Sep 2020 02:39:54 |
| User entered 'None (1)' | System | 09 Sep 2020 02:39:54 |

US3062128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:03:08

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-08T21:39:31', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '66cf3830-6047-46d6-9914-3ed12214256e' | System | 09 Sep 2020 02:39:54 |
| User entered 'No (N)' | System | 09 Sep 2020 02:39:54 |

US3062128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-08T21:39:37', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '66cf3830-6047-46d6-9914-3ed12214256e' | System | 09 Sep 2020 02:39:54 |
| User entered 'No (N)' | System | 09 Sep 2020 02:39:54 |

US3062128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:03:08

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-08T21:39:44', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '66cf3830-6047-46d6-9914-3ed12214256e' | System | 09 Sep 2020 02:39:54 |
| User entered 'None (1)' | System | 09 Sep 2020 02:39:54 |

US3062128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:03:08

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-08T21:39:49', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '66cf3830-6047-46d6-9914-3ed12214256e' | System | 09 Sep 2020 02:39:54 |
| User entered '08 Sep 2020 21:39' | System | 09 Sep 2020 02:39:54 |

US3062128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:03:08

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| User entered '08 Sep 2020 12:00' | System | 03 Sep 2020 17:24:02 |

US3062128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:03:08

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| User entered '09 Sep 2020 11:59' | System | 03 Sep 2020 17:24:02 |

US3062128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| Data entry locked. | System | 03 Sep 2020 17:24:02 |
| User entered 'Day 7' | System | 03 Sep 2020 17:24:02 |

US3062128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:03:08

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-09T21:41:20', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '7a7e40b1-0af3-4def-a08c-b34af3cf6847' | System | 10 Sep 2020 02:41:37 |
| User entered 'None (1)' | System | 10 Sep 2020 02:41:37 |

US3062128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:03:08

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-09T21:41:22', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '7a7e40b1-0af3-4def-a08c-b34af3cf6847' | System | 10 Sep 2020 02:41:37 |
| User entered 'No (N)' | System | 10 Sep 2020 02:41:37 |

US3062128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-09T21:41:25', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '7a7e40b1-0af3-4def-a08c-b34af3cf6847' | System | 10 Sep 2020 02:41:37 |
| User entered 'No (N)' | System | 10 Sep 2020 02:41:37 |

US3062128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:03:08

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-09T21:41:28', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '7a7e40b1-0af3-4def-a08c-b34af3cf6847' | System | 10 Sep 2020 02:41:37 |
| User entered 'None (1)' | System | 10 Sep 2020 02:41:37 |

US3062128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:03:08

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-09T21:41:33', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '7a7e40b1-0af3-4def-a08c-b34af3cf6847' | System | 10 Sep 2020 02:41:37 |
| User entered '09 Sep 2020 21:41' | System | 10 Sep 2020 02:41:37 |

US3062128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:03:08

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| User entered '09 Sep 2020 12:00' | System | 03 Sep 2020 17:24:02 |

US3062128

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:03:08

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| User entered '10 Sep 2020 11:59' | System | 03 Sep 2020 17:24:02 |

US3062128

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| Data entry locked. | System | 03 Sep 2020 17:24:02 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 03 Sep 2020 17:24:02 |

US3062128

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:08

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-03T12:52:02', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'f89b68a6-362f-47d6-982f-4dc85dbefce3' | System | 03 Sep 2020 17:52:33 |
| User entered 'None (0)' | System | 03 Sep 2020 17:52:33 |

US3062128

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:08

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-03T12:52:06', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'f89b68a6-362f-47d6-982f-4dc85dbefce3' | System | 03 Sep 2020 17:52:33 |
| User entered 'None (0)' | System | 03 Sep 2020 17:52:33 |

US3062128

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:08

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-03T12:52:09', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'f89b68a6-362f-47d6-982f-4dc85dbefce3' | System | 03 Sep 2020 17:52:33 |
| User entered 'None (0)' | System | 03 Sep 2020 17:52:33 |

US3062128

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:08

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-03T12:52:12', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'f89b68a6-362f-47d6-982f-4dc85dbefce3' | System | 03 Sep 2020 17:52:33 |
| User entered 'None (0)' | System | 03 Sep 2020 17:52:33 |

US3062128

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:08

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-03T12:52:16', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'f89b68a6-362f-47d6-982f-4dc85dbefce3' | System | 03 Sep 2020 17:52:33 |
| User entered 'None (0)' | System | 03 Sep 2020 17:52:33 |

US3062128

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:08

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-03T12:52:19', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'f89b68a6-362f-47d6-982f-4dc85dbefce3' | System | 03 Sep 2020 17:52:33 |
| User entered 'None (0)' | System | 03 Sep 2020 17:52:33 |

US3062128

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-03T12:52:23', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'f89b68a6-362f-47d6-982f-4dc85dbefce3' | System | 03 Sep 2020 17:52:33 |
| User entered 'No (N)' | System | 03 Sep 2020 17:52:33 |

US3062128

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:08

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-03T12:52:30', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'f89b68a6-362f-47d6-982f-4dc85dbefce3' | System | 03 Sep 2020 17:52:33 |
| User entered '03 Sep 2020 12:52' | System | 03 Sep 2020 17:52:33 |

US3062128

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:08

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| User entered '03 Sep 2020 12:35' | System | 03 Sep 2020 17:24:02 |

US3062128

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:08

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| User entered '03 Sep 2020 15:05' | System | 03 Sep 2020 17:24:02 |

US3062128

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| Data entry locked. | System | 03 Sep 2020 17:24:02 |
| User entered 'Day 1, after vaccination (at home)' | System | 03 Sep 2020 17:24:02 |

US3062128

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:08

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-03T21:27:02', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '59fb0bb2-ffe5-4061-98a0-95dc84ef4d75' | System | 04 Sep 2020 02:27:26 |
| User entered 'None (0)' | System | 04 Sep 2020 02:27:26 |

US3062128

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:08

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-03T21:27:04', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '59fb0bb2-ffe5-4061-98a0-95dc84ef4d75' | System | 04 Sep 2020 02:27:26 |
| User entered 'None (0)' | System | 04 Sep 2020 02:27:26 |

US3062128

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:08

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-03T21:27:07', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '59fb0bb2-ffe5-4061-98a0-95dc84ef4d75' | System | 04 Sep 2020 02:27:26 |
| User entered 'None (0)' | System | 04 Sep 2020 02:27:26 |

US3062128

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:08

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-03T21:27:10', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '59fb0bb2-ffe5-4061-98a0-95dc84ef4d75' | System | 04 Sep 2020 02:27:26 |
| User entered 'None (0)' | System | 04 Sep 2020 02:27:26 |

US3062128

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:08

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-03T21:27:12', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '59fb0bb2-ffe5-4061-98a0-95dc84ef4d75' | System | 04 Sep 2020 02:27:26 |
| User entered 'None (0)' | System | 04 Sep 2020 02:27:26 |

US3062128

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:08

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-03T21:27:14', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '59fb0bb2-ffe5-4061-98a0-95dc84ef4d75' | System | 04 Sep 2020 02:27:26 |
| User entered 'None (0)' | System | 04 Sep 2020 02:27:26 |

US3062128

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-03T21:27:17', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '59fb0bb2-ffe5-4061-98a0-95dc84ef4d75' | System | 04 Sep 2020 02:27:26 |
| User entered 'No (N)' | System | 04 Sep 2020 02:27:26 |

US3062128

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:08

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-03T21:27:23', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '59fb0bb2-ffe5-4061-98a0-95dc84ef4d75' | System | 04 Sep 2020 02:27:26 |
| User entered '03 Sep 2020 21:27' | System | 04 Sep 2020 02:27:26 |

US3062128

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:08

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| User entered '03 Sep 2020 16:00' | System | 03 Sep 2020 17:24:02 |

US3062128

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:08

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| User entered '04 Sep 2020 11:59' | System | 03 Sep 2020 17:24:02 |

US3062128

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| Data entry locked. | System | 03 Sep 2020 17:24:02 |
| User entered 'Day 2' | System | 03 Sep 2020 17:24:02 |

US3062128

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:08

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-04T21:15:30', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '1738deb1-332c-473f-8b39-c4235ccede62' | System | 05 Sep 2020 02:15:56 |
| User entered 'None (0)' | System | 05 Sep 2020 02:15:56 |

US3062128

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:08

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-04T21:15:32', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '1738deb1-332c-473f-8b39-c4235ccede62' | System | 05 Sep 2020 02:15:56 |
| User entered 'None (0)' | System | 05 Sep 2020 02:15:56 |

US3062128

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:08

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-04T21:15:35', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '1738deb1-332c-473f-8b39-c4235ccede62' | System | 05 Sep 2020 02:15:56 |
| User entered 'None (0)' | System | 05 Sep 2020 02:15:56 |

US3062128

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:08

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-04T21:15:38', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '1738deb1-332c-473f-8b39-c4235ccede62' | System | 05 Sep 2020 02:15:56 |
| User entered 'None (0)' | System | 05 Sep 2020 02:15:56 |

US3062128

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:08

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-04T21:15:40', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '1738deb1-332c-473f-8b39-c4235ccede62' | System | 05 Sep 2020 02:15:56 |
| User entered 'None (0)' | System | 05 Sep 2020 02:15:56 |

US3062128

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:08

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-04T21:15:42', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '1738deb1-332c-473f-8b39-c4235ccede62' | System | 05 Sep 2020 02:15:56 |
| User entered 'None (0)' | System | 05 Sep 2020 02:15:56 |

US3062128

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-04T21:15:45', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '1738deb1-332c-473f-8b39-c4235ccede62' | System | 05 Sep 2020 02:15:56 |
| User entered 'No (N)' | System | 05 Sep 2020 02:15:56 |

US3062128

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:08

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-04T21:15:51', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '1738deb1-332c-473f-8b39-c4235ccede62' | System | 05 Sep 2020 02:15:56 |
| User entered '04 Sep 2020 21:15' | System | 05 Sep 2020 02:15:56 |

US3062128

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:08

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| User entered '04 Sep 2020 12:00' | System | 03 Sep 2020 17:24:02 |

US3062128

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:08

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| User entered '05 Sep 2020 11:59' | System | 03 Sep 2020 17:24:02 |

US3062128

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| Data entry locked. | System | 03 Sep 2020 17:24:02 |
| User entered 'Day 3' | System | 03 Sep 2020 17:24:02 |

US3062128

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:08

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-05T20:57:46', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '5cc85908-d1c1-4886-9349-43bd961aa713' | System | 06 Sep 2020 01:58:12 |
| User entered 'None (0)' | System | 06 Sep 2020 01:58:12 |

US3062128

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:08

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-05T20:57:49', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '5cc85908-d1c1-4886-9349-43bd961aa713' | System | 06 Sep 2020 01:58:12 |
| User entered 'None (0)' | System | 06 Sep 2020 01:58:12 |

US3062128

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:08

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-05T20:57:51', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '5cc85908-d1c1-4886-9349-43bd961aa713' | System | 06 Sep 2020 01:58:12 |
| User entered 'None (0)' | System | 06 Sep 2020 01:58:12 |

US3062128

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:08

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-05T20:57:54', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '5cc85908-d1c1-4886-9349-43bd961aa713' | System | 06 Sep 2020 01:58:12 |
| User entered 'None (0)' | System | 06 Sep 2020 01:58:12 |

US3062128

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:08

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-05T20:57:57', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '5cc85908-d1c1-4886-9349-43bd961aa713' | System | 06 Sep 2020 01:58:12 |
| User entered 'None (0)' | System | 06 Sep 2020 01:58:12 |

US3062128

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:08

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-05T20:57:58', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '5cc85908-d1c1-4886-9349-43bd961aa713' | System | 06 Sep 2020 01:58:12 |
| User entered 'None (0)' | System | 06 Sep 2020 01:58:12 |

US3062128

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-05T20:58:01', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '5cc85908-d1c1-4886-9349-43bd961aa713' | System | 06 Sep 2020 01:58:12 |
| User entered 'No (N)' | System | 06 Sep 2020 01:58:12 |

US3062128

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:08

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-05T20:58:07', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '5cc85908-d1c1-4886-9349-43bd961aa713' | System | 06 Sep 2020 01:58:12 |
| User entered '05 Sep 2020 20:58' | System | 06 Sep 2020 01:58:12 |

US3062128

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:08

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| User entered '05 Sep 2020 12:00' | System | 03 Sep 2020 17:24:02 |

US3062128

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:08

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| User entered '06 Sep 2020 11:59' | System | 03 Sep 2020 17:24:02 |

US3062128

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| Data entry locked. | System | 03 Sep 2020 17:24:02 |
| User entered 'Day 4' | System | 03 Sep 2020 17:24:02 |

US3062128

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:08

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-06T21:38:18', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '74db10e0-4955-49d5-8aa6-b47d7d1111ac' | System | 07 Sep 2020 02:38:43 |
| User entered 'None (0)' | System | 07 Sep 2020 02:38:43 |

US3062128

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:08

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-06T21:38:21', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '74db10e0-4955-49d5-8aa6-b47d7d1111ac' | System | 07 Sep 2020 02:38:43 |
| User entered 'None (0)' | System | 07 Sep 2020 02:38:43 |

US3062128

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:08

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-06T21:38:23', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '74db10e0-4955-49d5-8aa6-b47d7d1111ac' | System | 07 Sep 2020 02:38:43 |
| User entered 'None (0)' | System | 07 Sep 2020 02:38:43 |

US3062128

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:08

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-06T21:38:25', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '74db10e0-4955-49d5-8aa6-b47d7d1111ac' | System | 07 Sep 2020 02:38:43 |
| User entered 'None (0)' | System | 07 Sep 2020 02:38:43 |

US3062128

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:08

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-06T21:38:27', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '74db10e0-4955-49d5-8aa6-b47d7d1111ac' | System | 07 Sep 2020 02:38:43 |
| User entered 'None (0)' | System | 07 Sep 2020 02:38:43 |

US3062128

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:08

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-06T21:38:29', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '74db10e0-4955-49d5-8aa6-b47d7d1111ac' | System | 07 Sep 2020 02:38:43 |
| User entered 'None (0)' | System | 07 Sep 2020 02:38:43 |

US3062128

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-06T21:38:32', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '74db10e0-4955-49d5-8aa6-b47d7d1111ac' | System | 07 Sep 2020 02:38:43 |
| User entered 'No (N)' | System | 07 Sep 2020 02:38:43 |

US3062128

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:08

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-06T21:38:40', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '74db10e0-4955-49d5-8aa6-b47d7d1111ac' | System | 07 Sep 2020 02:38:43 |
| User entered '06 Sep 2020 21:38' | System | 07 Sep 2020 02:38:43 |

US3062128

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:08

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| User entered '06 Sep 2020 12:00' | System | 03 Sep 2020 17:24:02 |

US3062128

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:08

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| User entered '07 Sep 2020 11:59' | System | 03 Sep 2020 17:24:02 |

US3062128

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| Data entry locked. | System | 03 Sep 2020 17:24:02 |
| User entered 'Day 5' | System | 03 Sep 2020 17:24:02 |

US3062128

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:08

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-07T21:16:29', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'aac06b68-32b4-46bd-a82c-3fee0ab2b3ee' | System | 08 Sep 2020 02:16:57 |
| User entered 'None (0)' | System | 08 Sep 2020 02:16:57 |

US3062128

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:08

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-07T21:16:31', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'aac06b68-32b4-46bd-a82c-3fee0ab2b3ee' | System | 08 Sep 2020 02:16:57 |
| User entered 'None (0)' | System | 08 Sep 2020 02:16:57 |

US3062128

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:08

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-07T21:16:34', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'aac06b68-32b4-46bd-a82c-3fee0ab2b3ee' | System | 08 Sep 2020 02:16:57 |
| User entered 'None (0)' | System | 08 Sep 2020 02:16:57 |

US3062128

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:08

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-07T21:16:36', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'aac06b68-32b4-46bd-a82c-3fee0ab2b3ee' | System | 08 Sep 2020 02:16:57 |
| User entered 'None (0)' | System | 08 Sep 2020 02:16:57 |

US3062128

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:08

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-07T21:16:39', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'aac06b68-32b4-46bd-a82c-3fee0ab2b3ee' | System | 08 Sep 2020 02:16:57 |
| User entered 'None (0)' | System | 08 Sep 2020 02:16:57 |

US3062128

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:08

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-07T21:16:41', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'aac06b68-32b4-46bd-a82c-3fee0ab2b3ee' | System | 08 Sep 2020 02:16:57 |
| User entered 'None (0)' | System | 08 Sep 2020 02:16:57 |

US3062128

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-07T21:16:44', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'aac06b68-32b4-46bd-a82c-3fee0ab2b3ee' | System | 08 Sep 2020 02:16:57 |
| User entered 'No (N)' | System | 08 Sep 2020 02:16:57 |

US3062128

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:08

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-07T21:16:52', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'aac06b68-32b4-46bd-a82c-3fee0ab2b3ee' | System | 08 Sep 2020 02:16:57 |
| User entered '07 Sep 2020 21:16' | System | 08 Sep 2020 02:16:57 |

US3062128

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:08

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| User entered '07 Sep 2020 12:00' | System | 03 Sep 2020 17:24:02 |

US3062128

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:08

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| User entered '08 Sep 2020 11:59' | System | 03 Sep 2020 17:24:02 |

US3062128

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| Data entry locked. | System | 03 Sep 2020 17:24:02 |
| User entered 'Day 6' | System | 03 Sep 2020 17:24:02 |

US3062128

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:08

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-08T21:39:54', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '5964d1a9-bf03-449c-9b15-148c2acfdb48' | System | 09 Sep 2020 02:40:46 |
| User entered 'None (0)' | System | 09 Sep 2020 02:40:46 |

US3062128

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:08

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-08T21:39:57', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '5964d1a9-bf03-449c-9b15-148c2acfdb48' | System | 09 Sep 2020 02:40:46 |
| User entered 'None (0)' | System | 09 Sep 2020 02:40:46 |

US3062128

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:08

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-08T21:40:00', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '5964d1a9-bf03-449c-9b15-148c2acfdb48' | System | 09 Sep 2020 02:40:46 |
| User entered 'None (0)' | System | 09 Sep 2020 02:40:46 |

US3062128

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:08

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-08T21:40:03', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '5964d1a9-bf03-449c-9b15-148c2acfdb48' | System | 09 Sep 2020 02:40:46 |
| User entered 'None (0)' | System | 09 Sep 2020 02:40:46 |

US3062128

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:08

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-08T21:40:06', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '5964d1a9-bf03-449c-9b15-148c2acfdb48' | System | 09 Sep 2020 02:40:46 |
| User entered 'None (0)' | System | 09 Sep 2020 02:40:46 |

US3062128

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:08

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-08T21:40:08', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '5964d1a9-bf03-449c-9b15-148c2acfdb48' | System | 09 Sep 2020 02:40:46 |
| User entered 'None (0)' | System | 09 Sep 2020 02:40:46 |

US3062128

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-08T21:40:11', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '5964d1a9-bf03-449c-9b15-148c2acfdb48' | System | 09 Sep 2020 02:40:46 |
| User entered 'No (N)' | System | 09 Sep 2020 02:40:46 |

US3062128

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:08

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-08T21:40:41', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '5964d1a9-bf03-449c-9b15-148c2acfdb48' | System | 09 Sep 2020 02:40:46 |
| User entered '08 Sep 2020 21:40' | System | 09 Sep 2020 02:40:46 |

US3062128

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:08

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| User entered '08 Sep 2020 12:00' | System | 03 Sep 2020 17:24:02 |

US3062128

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:08

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| User entered '09 Sep 2020 11:59' | System | 03 Sep 2020 17:24:02 |

US3062128

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| Data entry locked. | System | 03 Sep 2020 17:24:02 |
| User entered 'Day 7' | System | 03 Sep 2020 17:24:02 |

US3062128

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:08

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-09T21:41:38', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'b1678810-6471-4e96-9c70-623e2e798cca' | System | 10 Sep 2020 02:42:09 |
| User entered 'None (0)' | System | 10 Sep 2020 02:42:09 |

US3062128

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:08

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-09T21:41:41', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'b1678810-6471-4e96-9c70-623e2e798cca' | System | 10 Sep 2020 02:42:09 |
| User entered 'None (0)' | System | 10 Sep 2020 02:42:09 |

US3062128

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:08

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-09T21:41:45', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'b1678810-6471-4e96-9c70-623e2e798cca' | System | 10 Sep 2020 02:42:09 |
| User entered 'None (0)' | System | 10 Sep 2020 02:42:09 |

US3062128

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:08

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-09T21:41:48', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'b1678810-6471-4e96-9c70-623e2e798cca' | System | 10 Sep 2020 02:42:09 |
| User entered 'None (0)' | System | 10 Sep 2020 02:42:09 |

US3062128

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:08

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-09T21:41:51', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'b1678810-6471-4e96-9c70-623e2e798cca' | System | 10 Sep 2020 02:42:09 |
| User entered 'None (0)' | System | 10 Sep 2020 02:42:09 |

US3062128

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:08

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-09T21:41:53', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'b1678810-6471-4e96-9c70-623e2e798cca' | System | 10 Sep 2020 02:42:09 |
| User entered 'None (0)' | System | 10 Sep 2020 02:42:09 |

US3062128

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-09T21:41:56', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'b1678810-6471-4e96-9c70-623e2e798cca' | System | 10 Sep 2020 02:42:09 |
| User entered 'No (N)' | System | 10 Sep 2020 02:42:09 |

US3062128

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:08

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-09-09T21:42:02', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'b1678810-6471-4e96-9c70-623e2e798cca' | System | 10 Sep 2020 02:42:09 |
| User entered '09 Sep 2020 21:42' | System | 10 Sep 2020 02:42:09 |

US3062128

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:08

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| User entered '09 Sep 2020 12:00' | System | 03 Sep 2020 17:24:02 |

US3062128

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:08

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| User entered '10 Sep 2020 11:59' | System | 03 Sep 2020 17:24:02 |

US3062128

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:08

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:54:04 |
| User entered 'Yes (Y)' | Sherry Henning (b) (4) | 16 Sep 2020 21:18:47 |
| | (b) (4) | |

US3062128

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:08

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:54:04 |
| User entered '13 Sep 2020' | Sherry Henning (b) (4) | 16 Sep 2020 21:18:47 |

US3062128

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:08

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:54:04 |
| User entered 'Contact Made (CONTACT MADE)' | Sherry Henning (b) (4) | 16 Sep 2020 21:18:47 |

US3062128

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:08

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:54:04 |
| User entered empty. | Sherry Henning (b) (4) | 16 Sep 2020 21:18:47 |
| | (b) (4) | |

US3062128

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:08

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:54:07 |
| User entered 'Yes (Y)' | Sherry Henning (b) (4) | 16 Sep 2020 21:20:13 |
| | (b) (4) | |

US3062128

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:08

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User entered 'I' | System | 16 Sep 2020 21:20:13 |

US3062128

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:08

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:55:51 |
| User entered 'Yes (Y)' | Colton King (b) (4) | 17 Sep 2020 20:23:18 |
| | (b) (4) | |

US3062128

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:08

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:55:51 |
| User entered '17 Sep 2020' | Colton King (b) (4) | 17 Sep 2020 20:23:18 |
| | (b) (4) | |

US3062128

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:08

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:55:51 |
| User entered 'Contact Made (CONTACT MADE)' | Colton King (b) (4) | 17 Sep 2020 20:23:18 |

US3062128

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:08

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:55:51 |
| User entered empty. | Colton King (b) (4) | 17 Sep 2020 20:23:18 |
| | (b) (4) | |

US3062128

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:08

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:55:53 |
| User entered 'Yes (Y)' | Colton King (b) (4) | 17 Sep 2020 20:23:08 |
| | (b) (4) | |

US3062128

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:08

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User entered 'I' | System | 17 Sep 2020 20:23:08 |

US3062128

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:08

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Oct 2020 16:33:50 |
| User entered 'Yes (Y)' | Janna Martinez (b) (4) | 30 Sep 2020 16:13:58 |
| | (b) (4) | |

US3062128

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:08

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Oct 2020 16:33:50 |
| User entered '24 Sep 2020' | Janna Martinez (b) (4) | 30 Sep 2020 16:13:58 |
| | (b) (4) | |

US3062128

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:08

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Oct 2020 16:33:50 |
| User entered 'Contact Made (CONTACT MADE)' | Janna Martinez (b) (4) | 30 Sep 2020 16:13:58 |
| | (b) (4) | |

US3062128

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:08

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Oct 2020 16:33:50 |
| User entered empty. | Janna Martinez (b) (4) | 30 Sep 2020 16:13:58 |
| | (b) (4) | |

US3062128

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:08

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:47 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Oct 2020 16:34:07 |
| User entered 'Yes (Y)' | Janna Martinez (b) (4) | 30 Sep 2020 16:14:02 |
| | (b) (4) | |

US3062128

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:08

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User entered 'I' | System | 30 Sep 2020 16:14:02 |

US3062128

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:03:08

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:48 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Oct 2020 16:34:51 |
| User entered 'Yes (Y)' | Janna Martinez (b) (4) | 30 Sep 2020 16:14:18 |
| | (b) (4) | |

US3062128

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:48 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Oct 2020 16:34:51 |
| User entered '30 Sep 2020' | Janna Martinez (b) (4) | 30 Sep 2020 16:14:18 |
| | (b) (4) | |

US3062128

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|--------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:48 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Oct 2020 16:34:51 |
| User entered 'Clinic (Clinic)' | Janna Martinez (b) (4) | 30 Sep 2020 16:14:18 |
| | (b) (4) | |

US3062128

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:03:08

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User entered 'VISIT3' | System | 30 Sep 2020 16:14:18 |

US3062128

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:08

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:48 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Oct 2020 16:35:55 |
| User entered 'Yes (Y)' | Janna Martinez (b) (4) | 30 Sep 2020 16:14:55 |
| | (b) (4) | |

US3062128

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:08

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:48 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Oct 2020 16:35:55 |
| User entered '30 Sep 2020' | Janna Martinez (b) (4) | 30 Sep 2020 16:14:55 |
| | (b) (4) | |

US3062128

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:48 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Oct 2020 16:35:55 |
| User entered '10:00' | Janna Martinez (b) (4) | 30 Sep 2020 16:14:55 |
| | (b) (4) | |

US3062128

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User entered '30 Sep 2020 10:00' | System | 30 Sep 2020 16:14:55 |

US3062128

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:08

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:48 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Oct 2020 16:35:55 |
| User entered '97.7' F | Janna Martinez (b) (4) | 30 Sep 2020 16:14:55 |
| | (b) (4) | |

US3062128

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:08

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:48 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Oct 2020 16:35:55 |
| User entered 'Oral (Oral)' | Janna Martinez (b) (4) | 30 Sep 2020 16:14:55 |
| | (b) (4) | |

US3062128

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:08

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:48 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Oct 2020 16:35:55 |
| User entered empty. | Janna Martinez (b) (4) | 30 Sep 2020 16:14:55 |
| | (b) (4) | |

US3062128

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:08

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:48 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Oct 2020 16:35:55 |
| User entered '64' | Janna Martinez (b) (4) | 30 Sep 2020 16:14:55 |
| | (b) (4) | |

US3062128

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:08

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User entered 'bpm' | System | 30 Sep 2020 16:14:55 |

US3062128

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:48 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Oct 2020 16:35:55 |
| User entered '16' | Janna Martinez (b) (4) | 30 Sep 2020 16:14:55 |
| | (b) (4) | |

US3062128

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:08

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User entered 'breaths/min' | System | 30 Sep 2020 16:14:55 |

US3062128

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:08

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:48 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Oct 2020 16:35:55 |
| User entered '117' | Janna Martinez (b) (4) | 30 Sep 2020 16:14:55 |
| | (b) (4) | |

US3062128

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:08

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User entered 'mmHg' | System | 30 Sep 2020 16:14:55 |

US3062128

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:08

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:48 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Oct 2020 16:35:55 |
| User entered '72' | Janna Martinez (b) (4) | 30 Sep 2020 16:14:55 |
| | (b) (4) | |

US3062128

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:08

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User entered 'mmHg' | System | 30 Sep 2020 16:14:55 |

US3062128

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:08

[Height \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| | | |

US3062128

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:08

[Weight \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| | | |

US3062128

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:03:08

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:48 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Oct 2020 16:36:03 |
| User entered 'No (N)' | Janna Martinez (b) (4) | 30 Sep 2020 16:15:07 |
| | (b) (4) | |

US3062128

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:03:08

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:48 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Oct 2020 16:36:03 |
| User entered empty. | Janna Martinez (b) (4) | 30 Sep 2020 16:15:07 |
| | (b) (4) | |

US3062128

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:03:08

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:48 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Oct 2020 16:36:07 |
| User entered 'Yes (Y)' | Janna Martinez (b) (4) | 30 Sep 2020 16:15:16 |
| | (b) (4) | |

US3062128

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:03:08

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:48 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Oct 2020 16:36:07 |
| User entered '30 Sep 2020' | Janna Martinez (b) (4) | 30 Sep 2020 16:15:16 |
| | (b) (4) | |

US3062128

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:03:08

[Collection time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:48 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Oct 2020 16:36:07 |
| User entered '10:30' | Janna Martinez (b) (4) | 30 Sep 2020 16:15:16 |
| | (b) (4) | |

US3062128

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:03:08

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User entered '30 Sep 2020 10:30' | System | 30 Sep 2020 16:15:16 |

US3062128

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:08

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 15 Feb 2021 15:28:48 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Oct 2020 16:36:10 |
| User entered 'Yes (Y)' | Janna Martinez (b) (4) | 30 Sep 2020 16:15:19 |
| | (b) (4) | |

US3062128

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:08

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User entered 'I' | System | 30 Sep 2020 16:15:19 |

US3062128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| Data entry locked. | System | 06 Aug 2020 22:01:06 |
| User entered 'Day 64' | System | 06 Aug 2020 22:01:06 |

US3062128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-10-06T08:09:58', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '130d49ae-a5e3-43bf-8374-f41135ed67ec' | System | 06 Oct 2020 13:10:23 |
| User entered 'No (N)' | System | 06 Oct 2020 13:10:23 |

US3062128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-10-06T08:10:04', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '130d49ae-a5e3-43bf-8374-f41135ed67ec' | System | 06 Oct 2020 13:10:23 |
| User entered 'No (N)' | System | 06 Oct 2020 13:10:23 |

US3062128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-10-06T08:10:20', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '130d49ae-a5e3-43bf-8374-f41135ed67ec' | System | 06 Oct 2020 13:10:23 |
| User entered '06 Oct 2020 08:10:20' | System | 06 Oct 2020 13:10:23 |

US3062128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| Data entry locked. | System | 06 Aug 2020 22:01:06 |
| User entered '06 Oct 2020 00:01' | System | 06 Aug 2020 22:01:06 |

US3062128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| Data entry locked. | System | 06 Aug 2020 22:01:06 |
| User entered '10 Oct 2020 23:59' | System | 06 Aug 2020 22:01:06 |

US3062128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| Data entry locked. | System | 06 Aug 2020 22:01:06 |
| User entered 'Day 71' | System | 06 Aug 2020 22:01:06 |

US3062128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-10-14T11:54:18', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '4e1acbde-960d-4820-98b2-3a6bec57e4bd' | System | 14 Oct 2020 16:54:35 |
| User entered 'No (N)' | System | 14 Oct 2020 16:54:35 |

US3062128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-10-14T11:54:22', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '4e1acbde-960d-4820-98b2-3a6bec57e4bd' | System | 14 Oct 2020 16:54:35 |
| User entered 'No (N)' | System | 14 Oct 2020 16:54:35 |

US3062128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-10-14T11:54:31', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '4e1acbde-960d-4820-98b2-3a6bec57e4bd' | System | 14 Oct 2020 16:54:35 |
| User entered '14 Oct 2020 11:54:31' | System | 14 Oct 2020 16:54:35 |

US3062128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| Data entry locked. | System | 06 Aug 2020 22:01:06 |
| User entered '13 Oct 2020 00:01' | System | 06 Aug 2020 22:01:06 |

US3062128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| Data entry locked. | System | 06 Aug 2020 22:01:06 |
| User entered '17 Oct 2020 23:59' | System | 06 Aug 2020 22:01:06 |

US3062128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| Data entry locked. | System | 06 Aug 2020 22:01:06 |
| User entered 'Day 78' | System | 06 Aug 2020 22:01:06 |

US3062128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-10-20T07:22:08', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'd7b39460-6816-4f0f-a298-3468579572be' | System | 20 Oct 2020 12:22:33 |
| User entered 'No (N)' | System | 20 Oct 2020 12:22:33 |

US3062128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-10-20T07:22:18', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'd7b39460-6816-4f0f-a298-3468579572be' | System | 20 Oct 2020 12:22:33 |
| User entered 'No (N)' | System | 20 Oct 2020 12:22:33 |

US3062128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-10-20T07:22:29', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'd7b39460-6816-4f0f-a298-3468579572be' | System | 20 Oct 2020 12:22:33 |
| User entered '20 Oct 2020 07:22:29' | System | 20 Oct 2020 12:22:33 |

US3062128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| Data entry locked. | System | 06 Aug 2020 22:01:06 |
| User entered '20 Oct 2020 00:01' | System | 06 Aug 2020 22:01:06 |

US3062128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| Data entry locked. | System | 06 Aug 2020 22:01:06 |
| User entered '24 Oct 2020 23:59' | System | 06 Aug 2020 22:01:06 |

US3062128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| Data entry locked. | System | 06 Aug 2020 22:01:06 |
| User entered 'Day 92' | System | 06 Aug 2020 22:01:06 |

US3062128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-11-04T09:32:37', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'ba8c5b9b-3278-40d3-b897-a8f0dfa65e1e' | System | 04 Nov 2020 15:32:58 |
| User entered 'No (N)' | System | 04 Nov 2020 15:32:58 |

US3062128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-11-04T09:32:45', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'ba8c5b9b-3278-40d3-b897-a8f0dfa65e1e' | System | 04 Nov 2020 15:32:58 |
| User entered 'No (N)' | System | 04 Nov 2020 15:32:58 |

US3062128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-11-04T09:32:51', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'ba8c5b9b-3278-40d3-b897-a8f0dfa65e1e' | System | 04 Nov 2020 15:32:58 |
| User entered '04 Nov 2020 09:32:51' | System | 04 Nov 2020 15:32:58 |

US3062128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| Data entry locked. | System | 06 Aug 2020 22:01:06 |
| User entered '03 Nov 2020 00:01' | System | 06 Aug 2020 22:01:06 |

US3062128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| Data entry locked. | System | 06 Aug 2020 22:01:06 |
| User entered '07 Nov 2020 23:59' | System | 06 Aug 2020 22:01:06 |

US3062128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| Data entry locked. | System | 06 Aug 2020 22:01:06 |
| User entered 'Day 99' | System | 06 Aug 2020 22:01:06 |

US3062128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-11-11T07:33:53', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '37ff4050-27ea-4132-a518-871dc370d59e' | System | 11 Nov 2020 13:34:05 |
| User entered 'No (N)' | System | 11 Nov 2020 13:34:05 |

US3062128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-11-11T07:33:58', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '37ff4050-27ea-4132-a518-871dc370d59e' | System | 11 Nov 2020 13:34:05 |
| User entered 'No (N)' | System | 11 Nov 2020 13:34:05 |

US3062128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-11-11T07:34:02', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '37ff4050-27ea-4132-a518-871dc370d59e' | System | 11 Nov 2020 13:34:05 |
| User entered '11 Nov 2020 07:34:02' | System | 11 Nov 2020 13:34:05 |

US3062128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| Data entry locked. | System | 06 Aug 2020 22:01:06 |
| User entered '10 Nov 2020 00:01' | System | 06 Aug 2020 22:01:06 |

US3062128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:58:28 |
| Data entry locked. | System | 06 Aug 2020 22:01:06 |
| User entered '14 Nov 2020 23:59' | System | 06 Aug 2020 22:01:06 |

US3062128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:09:27 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 15:16:02 |
| Data entry locked. | System | 06 Aug 2020 22:01:06 |
| User entered 'Day 106' | System | 06 Aug 2020 22:01:06 |

US3062128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:09:27 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:09:27 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:09:27 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:09:27 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

Fever (Temperature \geq 100.4°F/38°C)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:09:27 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Chills](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:09:27 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Cough](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:09:27 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Shortness of breath](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:09:27 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Difficulty breathing](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:09:27 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Fatigue](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:09:27 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Muscle aches](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:09:27 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Body aches](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:09:27 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Headache](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:09:27 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[New loss of taste](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:09:27 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[New loss of smell](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:09:27 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Sore throat](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:09:27 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Congestion](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:09:27 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Runny nose](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:09:27 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Nausea](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:09:27 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Vomiting](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:09:27 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Diarrhea](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:09:27 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:09:27 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:09:27 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:09:27 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:09:27 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:09:27 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 15:16:02 |
| Data entry locked. | System | 06 Aug 2020 22:01:06 |
| User entered '17 Nov 2020 00:01' | System | 06 Aug 2020 22:01:06 |

US3062128

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:09:27 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 15:16:02 |
| Data entry locked. | System | 06 Aug 2020 22:01:06 |
| User entered '21 Nov 2020 23:59' | System | 06 Aug 2020 22:01:06 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered 'Day 110' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[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 (ebb02651d2868128)', Time: '2020-11-25T12:24:40', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '6550dd5b-4ccf-49b8-8423-6ba421e93ba0' | System | 25 Nov 2020 18:24:54 |
| User entered 'No (N)' | System | 25 Nov 2020 18:24:54 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Have you been exposed to someone with 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 (ebb02651d2868128)', Time: '2020-11-25T12:24:46', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '6550dd5b-4ccf-49b8-8423-6ba421e93ba0' | System | 25 Nov 2020 18:24:54 |
| User entered 'No (N)' | System | 25 Nov 2020 18:24:54 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-11-25T12:24:51', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '6550dd5b-4ccf-49b8-8423-6ba421e93ba0' | System | 25 Nov 2020 18:24:54 |
| User entered '25 Nov 2020 12:24:51' | System | 25 Nov 2020 18:24:54 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '21 Nov 2020 00:01' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '25 Nov 2020 23:59' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered 'Day 117' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[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 (ebb02651d2868128)', Time: '2020-12-01T18:00:33', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'b15f9523-c2af-4176-ac0a-640fa58dca45' | System | 02 Dec 2020 00:00:59 |
| User entered 'No (N)' | System | 02 Dec 2020 00:00:59 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Have you been exposed to someone with 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 (ebb02651d2868128)', Time: '2020-12-01T18:00:44', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'b15f9523-c2af-4176-ac0a-640fa58dca45' | System | 02 Dec 2020 00:00:59 |
| User entered 'No (N)' | System | 02 Dec 2020 00:00:59 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-12-01T18:00:56', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'b15f9523-c2af-4176-ac0a-640fa58dca45' | System | 02 Dec 2020 00:00:59 |
| User entered '01 Dec 2020 18:00:56' | System | 02 Dec 2020 00:00:59 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '28 Nov 2020 00:01' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '02 Dec 2020 23:59' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered 'Day 124' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[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 (ebb02651d2868128)', Time: '2020-12-09T12:42:01', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '7b03ce8e-8394-4eb7-8789-1650aec153ca' | System | 09 Dec 2020 18:42:14 |
| User entered 'No (N)' | System | 09 Dec 2020 18:42:14 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Have you been exposed to someone with 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 (ebb02651d2868128)', Time: '2020-12-09T12:42:08', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '7b03ce8e-8394-4eb7-8789-1650aec153ca' | System | 09 Dec 2020 18:42:14 |
| User entered 'No (N)' | System | 09 Dec 2020 18:42:14 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-12-09T12:42:11', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '7b03ce8e-8394-4eb7-8789-1650aec153ca' | System | 09 Dec 2020 18:42:14 |
| User entered '09 Dec 2020 12:42:11' | System | 09 Dec 2020 18:42:14 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '05 Dec 2020 00:01' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '09 Dec 2020 23:59' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered 'Day 131' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[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 (ebb02651d2868128)', Time: '2020-12-12T07:45:07', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'b9a85734-92dc-4549-bba0-d2d4bc4b0849' | System | 12 Dec 2020 13:45:21 |
| User entered 'No (N)' | System | 12 Dec 2020 13:45:21 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

Have you been exposed to someone with 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 (ebb02651d2868128)', Time: '2020-12-12T07:45:12', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'b9a85734-92dc-4549-bba0-d2d4bc4b0849' | System | 12 Dec 2020 13:45:21 |
| User entered 'No (N)' | System | 12 Dec 2020 13:45:21 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ebb02651d2868128)', Time: '2020-12-12T07:45:17', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'b9a85734-92dc-4549-bba0-d2d4bc4b0849' | System | 12 Dec 2020 13:45:21 |
| User entered '12 Dec 2020 07:45:17' | System | 12 Dec 2020 13:45:21 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '12 Dec 2020 00:01' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '16 Dec 2020 23:59' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered 'Day 138' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[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 (e415f2ec5194138d)', Time: '2020-12-23T09:17:14', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'f7dbc727-0eb6-4ce8-9427-2d48ab2f165e' | System | 23 Dec 2020 15:17:23 |
| User entered 'No (N)' | System | 23 Dec 2020 15:17:23 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

Have you been exposed to someone with 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 (e415f2ec5194138d)', Time: '2020-12-23T09:17:17', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'f7dbc727-0eb6-4ce8-9427-2d48ab2f165e' | System | 23 Dec 2020 15:17:23 |
| User entered 'No (N)' | System | 23 Dec 2020 15:17:23 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e415f2ec5194138d)', Time: '2020-12-23T09:17:21', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'f7dbc727-0eb6-4ce8-9427-2d48ab2f165e' | System | 23 Dec 2020 15:17:23 |
| User entered '23 Dec 2020 09:17:21' | System | 23 Dec 2020 15:17:23 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '19 Dec 2020 00:01' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '23 Dec 2020 23:59' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered 'Day 145' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[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 (e415f2ec5194138d)', Time: '2020-12-26T07:31:34', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'd7a4693b-2383-466e-a992-e80e6f653686' | System | 26 Dec 2020 13:31:48 |
| User entered 'No (N)' | System | 26 Dec 2020 13:31:48 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

Have you been exposed to someone with 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 (e415f2ec5194138d)', Time: '2020-12-26T07:31:40', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'd7a4693b-2383-466e-a992-e80e6f653686' | System | 26 Dec 2020 13:31:48 |
| User entered 'No (N)' | System | 26 Dec 2020 13:31:48 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e415f2ec5194138d)', Time: '2020-12-26T07:31:47', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'd7a4693b-2383-466e-a992-e80e6f653686' | System | 26 Dec 2020 13:31:48 |
| User entered '26 Dec 2020 07:31:47' | System | 26 Dec 2020 13:31:48 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '26 Dec 2020 00:01' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '30 Dec 2020 23:59' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered 'Day 152' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[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 (e415f2ec5194138d)', Time: '2021-01-02T07:32:52', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'c889479c-1d45-4173-9881-244fedb73d2f' | System | 02 Jan 2021 13:33:02 |
| User entered 'No (N)' | System | 02 Jan 2021 13:33:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

Have you been exposed to someone with 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 (e415f2ec5194138d)', Time: '2021-01-02T07:32:56', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'c889479c-1d45-4173-9881-244fedb73d2f' | System | 02 Jan 2021 13:33:02 |
| User entered 'No (N)' | System | 02 Jan 2021 13:33:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e415f2ec5194138d)', Time: '2021-01-02T07:33:01', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'c889479c-1d45-4173-9881-244fedb73d2f' User entered '02 Jan 2021 07:33:01' | System | 02 Jan 2021 13:33:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '02 Jan 2021 00:01' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '06 Jan 2021 23:59' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered 'Day 159' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[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 (e415f2ec5194138d)', Time: '2021-01-09T07:33:15', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'ecbdf3fa-8574-4e5b-9405-e73add67992a' | System | 09 Jan 2021 13:33:41 |
| User entered 'No (N)' | System | 09 Jan 2021 13:33:41 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

Have you been exposed to someone with 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 (e415f2ec5194138d)', Time: '2021-01-09T07:33:29', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'ecbdf3fa-8574-4e5b-9405-e73add67992a' | System | 09 Jan 2021 13:33:41 |
| User entered 'No (N)' | System | 09 Jan 2021 13:33:41 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e415f2ec5194138d)', Time: '2021-01-09T07:33:42', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'ecbdf3fa-8574-4e5b-9405-e73add67992a' User entered '09 Jan 2021 07:33:42' | System | 09 Jan 2021 13:33:41 |
| | System | 09 Jan 2021 13:33:41 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '09 Jan 2021 00:01' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '13 Jan 2021 23:59' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered 'Day 166' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[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 (e415f2ec5194138d)', Time: '2021-01-16T06:33:04', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '37756eee-01ff-4bd8-9ec6-9f1af534cc97' | System | 16 Jan 2021 12:33:10 |
| User entered 'No (N)' | System | 16 Jan 2021 12:33:10 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

Have you been exposed to someone with 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 (e415f2ec5194138d)', Time: '2021-01-16T06:33:09', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '37756eee-01ff-4bd8-9ec6-9f1af534cc97' | System | 16 Jan 2021 12:33:10 |
| User entered 'No (N)' | System | 16 Jan 2021 12:33:10 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e415f2ec5194138d)', Time: '2021-01-16T06:33:12', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '37756eee-01ff-4bd8-9ec6-9f1af534cc97' | System | 16 Jan 2021 12:33:10 |
| User entered '16 Jan 2021 06:33:12' | System | 16 Jan 2021 12:33:10 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '16 Jan 2021 00:01' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '20 Jan 2021 23:59' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered 'Day 173' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[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 (e415f2ec5194138d)', Time: '2021-01-23T06:20:24', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '3ff58a8a-f9a5-4c6c-b6cc-888e6921fd69' | System | 23 Jan 2021 12:20:29 |
| User entered 'No (N)' | System | 23 Jan 2021 12:20:29 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

Have you been exposed to someone with 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 (e415f2ec5194138d)', Time: '2021-01-23T06:20:28', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '3ff58a8a-f9a5-4c6c-b6cc-888e6921fd69' | System | 23 Jan 2021 12:20:29 |
| User entered 'No (N)' | System | 23 Jan 2021 12:20:29 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e415f2ec5194138d)', Time: '2021-01-23T06:20:31', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '3ff58a8a-f9a5-4c6c-b6cc-888e6921fd69' | System | 23 Jan 2021 12:20:29 |
| User entered '23 Jan 2021 06:20:31' | System | 23 Jan 2021 12:20:29 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '23 Jan 2021 00:01' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '27 Jan 2021 23:59' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered 'Day 180' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[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 (e415f2ec5194138d)', Time: '2021-01-31T15:05:47', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '40af0f7b-f6f7-46bc-9142-1447fda96325' | System | 31 Jan 2021 21:06:04 |
| User entered 'No (N)' | System | 31 Jan 2021 21:06:04 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

Have you been exposed to someone with 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 (e415f2ec5194138d)', Time: '2021-01-31T15:05:57', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '40af0f7b-f6f7-46bc-9142-1447fda96325' | System | 31 Jan 2021 21:06:04 |
| User entered 'No (N)' | System | 31 Jan 2021 21:06:04 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e415f2ec5194138d)', Time: '2021-01-31T15:06:00', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '40af0f7b-f6f7-46bc-9142-1447fda96325' | System | 31 Jan 2021 21:06:04 |
| User entered '31 Jan 2021 15:06:00' | System | 31 Jan 2021 21:06:04 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '30 Jan 2021 00:01' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '03 Feb 2021 23:59' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered 'Day 187' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[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 (e415f2ec5194138d)', Time: '2021-02-07T07:24:07', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '92a05f93-8eeb-4b8a-b0f1-f2371b69e362' | System | 07 Feb 2021 13:24:25 |
| User entered 'No (N)' | System | 07 Feb 2021 13:24:25 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

Have you been exposed to someone with 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 (e415f2ec5194138d)', Time: '2021-02-07T07:24:12', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '92a05f93-8eeb-4b8a-b0f1-f2371b69e362' | System | 07 Feb 2021 13:24:25 |
| User entered 'No (N)' | System | 07 Feb 2021 13:24:25 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e415f2ec5194138d)', Time: '2021-02-07T07:24:23', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '92a05f93-8eeb-4b8a-b0f1-f2371b69e362' | System | 07 Feb 2021 13:24:25 |
| User entered '07 Feb 2021 07:24:23' | System | 07 Feb 2021 13:24:25 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '06 Feb 2021 00:01' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '10 Feb 2021 23:59' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered 'Day 194' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[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 (e415f2ec5194138d)', Time: '2021-02-13T00:03:57', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'b3402fb5-5572-4378-aa26-e864b55b18f6' | System | 13 Feb 2021 06:04:11 |
| User entered 'No (N)' | System | 13 Feb 2021 06:04:11 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Have you been exposed to someone with 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 (e415f2ec5194138d)', Time: '2021-02-13T00:04:03', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'b3402fb5-5572-4378-aa26-e864b55b18f6' | System | 13 Feb 2021 06:04:11 |
| User entered 'No (N)' | System | 13 Feb 2021 06:04:11 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e415f2ec5194138d)', Time: '2021-02-13T00:04:10', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'b3402fb5-5572-4378-aa26-e864b55b18f6' | System | 13 Feb 2021 06:04:11 |
| User entered '13 Feb 2021 00:04:10' | System | 13 Feb 2021 06:04:11 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '13 Feb 2021 00:01' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '17 Feb 2021 23:59' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered 'Day 201' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[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 (e415f2ec5194138d)', Time: '2021-02-20T10:21:50', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '226619fb-eec8-430c-bac9-aa4d98ab8eb4' | System | 20 Feb 2021 16:21:59 |
| User entered 'No (N)' | System | 20 Feb 2021 16:21:59 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

Have you been exposed to someone with 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 (e415f2ec5194138d)', Time: '2021-02-20T10:21:53', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '226619fb-eec8-430c-bac9-aa4d98ab8eb4' | System | 20 Feb 2021 16:21:59 |
| User entered 'No (N)' | System | 20 Feb 2021 16:21:59 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e415f2ec5194138d)', Time: '2021-02-20T10:21:56', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '226619fb-eec8-430c-bac9-aa4d98ab8eb4' | System | 20 Feb 2021 16:21:59 |
| User entered '20 Feb 2021 10:21:56' | System | 20 Feb 2021 16:21:59 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '20 Feb 2021 00:01' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '24 Feb 2021 23:59' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered 'Day 208' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[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 (e415f2ec5194138d)', Time: '2021-02-27T00:38:04-06:00', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'cb66bf5c-e81f-4b2d-a155-150536ea4da8' | System | 27 Feb 2021 06:38:14 |
| User entered 'No (N)' | System | 27 Feb 2021 06:38:14 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

Have you been exposed to someone with 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 (e415f2ec5194138d)', Time: '2021-02-27T00:38:06-06:00', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'cb66bf5c-e81f-4b2d-a155-150536ea4da8' | System | 27 Feb 2021 06:38:14 |
| User entered 'No (N)' | System | 27 Feb 2021 06:38:14 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e415f2ec5194138d)', Time: '2021-02-27T00:38:13-06:00', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'cb66bf5c-e81f-4b2d-a155-150536ea4da8' | System | 27 Feb 2021 06:38:14 |
| User entered '27 Feb 2021 00:38:13' | System | 27 Feb 2021 06:38:14 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '27 Feb 2021 00:01' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '03 Mar 2021 23:59' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered 'Day 215' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[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 (e415f2ec5194138d)', Time: '2021-03-06T07:30:59-06:00', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '3777f09e-2bc8-4288-b3f3-9a398fd6f9ef' User entered 'No (N)' | System | 06 Mar 2021 13:31:18 |
| | System | 06 Mar 2021 13:31:18 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

Have you been exposed to someone with 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 (e415f2ec5194138d)', Time: '2021-03-06T07:31:08-06:00', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '3777f09e-2bc8-4288-b3f3-9a398fd6f9ef' User entered 'No (N)' | System | 06 Mar 2021 13:31:18 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e415f2ec5194138d)', Time: '2021-03-06T07:31:15-06:00', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '3777f09e-2bc8-4288-b3f3-9a398fd6f9ef' | System | 06 Mar 2021 13:31:18 |
| User entered '06 Mar 2021 07:31:15' | System | 06 Mar 2021 13:31:18 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '06 Mar 2021 00:01' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '10 Mar 2021 23:59' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered 'Day 222' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[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 (e415f2ec5194138d)', Time: '2021-03-13T06:49:26-06:00', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '47e3b9b7-ad99-4298-af54-370a24a6f433' | System | 13 Mar 2021 12:49:43 |
| User entered 'No (N)' | System | 13 Mar 2021 12:49:43 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

Have you been exposed to someone with 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 (e415f2ec5194138d)', Time: '2021-03-13T06:49:35-06:00', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '47e3b9b7-ad99-4298-af54-370a24a6f433' | System | 13 Mar 2021 12:49:43 |
| User entered 'No (N)' | System | 13 Mar 2021 12:49:43 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e415f2ec5194138d)', Time: '2021-03-13T06:49:42-06:00', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '47e3b9b7-ad99-4298-af54-370a24a6f433' | System | 13 Mar 2021 12:49:43 |
| User entered '13 Mar 2021 06:49:42' | System | 13 Mar 2021 12:49:43 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '13 Mar 2021 00:01' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '17 Mar 2021 23:59' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered 'Day 229' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[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 (e415f2ec5194138d)', Time: '2021-03-21T09:32:18-05:00', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'a479822c-aa6b-496b-9040-2c06040106b3' | System | 21 Mar 2021 14:32:25 |
| User entered 'No (N)' | System | 21 Mar 2021 14:32:25 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

Have you been exposed to someone with 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 (e415f2ec5194138d)', Time: '2021-03-21T09:32:20-05:00', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'a479822c-aa6b-496b-9040-2c06040106b3' | System | 21 Mar 2021 14:32:25 |
| User entered 'No (N)' | System | 21 Mar 2021 14:32:25 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e415f2ec5194138d)', Time: '2021-03-21T09:32:23-05:00', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'a479822c-aa6b-496b-9040-2c06040106b3' | System | 21 Mar 2021 14:32:25 |
| User entered '21 Mar 2021 09:32:23' | System | 21 Mar 2021 14:32:25 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '20 Mar 2021 00:01' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '24 Mar 2021 23:59' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered 'Day 236' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[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 (e415f2ec5194138d)', Time: '2021-03-28T07:44:37-05:00', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'a2e613e2-d815-471d-9948-10e9e69648dc' | System | 28 Mar 2021 12:44:50 |
| User entered 'No (N)' | System | 28 Mar 2021 12:44:50 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

Have you been exposed to someone with 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 (e415f2ec5194138d)', Time: '2021-03-28T07:44:41-05:00', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'a2e613e2-d815-471d-9948-10e9e69648dc' | System | 28 Mar 2021 12:44:50 |
| User entered 'No (N)' | System | 28 Mar 2021 12:44:50 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e415f2ec5194138d)', Time: '2021-03-28T07:44:48-05:00', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'a2e613e2-d815-471d-9948-10e9e69648dc' User entered '28 Mar 2021 07:44:48' | System | 28 Mar 2021 12:44:50 |
| | System | 28 Mar 2021 12:44:50 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '27 Mar 2021 00:01' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '31 Mar 2021 23:59' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered 'Day 243' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[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 (e415f2ec5194138d)', Time: '2021-04-05T13:46:02-05:00', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '50935eb2-98ad-4c31-8c09-e9ade6bd3bb1' User entered 'No (N)' | System | 05 Apr 2021 18:46:10 |
| | System | 05 Apr 2021 18:46:10 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

Have you been exposed to someone with 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 (e415f2ec5194138d)', Time: '2021-04-05T13:46:05-05:00', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '50935eb2-98ad-4c31-8c09-e9ade6bd3bb1' User entered 'No (N)' | System | 05 Apr 2021 18:46:10 |
| | System | 05 Apr 2021 18:46:10 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e415f2ec5194138d)', Time: '2021-04-05T13:46:08-05:00', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '50935eb2-98ad-4c31-8c09-e9ade6bd3bb1' User entered '05 Apr 2021 13:46:08' | System | 05 Apr 2021 18:46:10 |
| | System | 05 Apr 2021 18:46:10 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '03 Apr 2021 00:01' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '07 Apr 2021 23:59' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered 'Day 250' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[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 (e415f2ec5194138d)', Time: '2021-04-12T11:43:15-05:00', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '71b9a77e-4705-4ad3-b55f-8fe9790edf46' | System | 12 Apr 2021 16:43:41 |
| User entered 'No (N)' | System | 12 Apr 2021 16:43:41 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

Have you been exposed to someone with 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 (e415f2ec5194138d)', Time: '2021-04-12T11:43:18-05:00', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '71b9a77e-4705-4ad3-b55f-8fe9790edf46' | System | 12 Apr 2021 16:43:41 |
| User entered 'No (N)' | System | 12 Apr 2021 16:43:41 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e415f2ec5194138d)', Time: '2021-04-12T11:43:33-05:00', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '71b9a77e-4705-4ad3-b55f-8fe9790edf46' | System | 12 Apr 2021 16:43:41 |
| User entered '12 Apr 2021 11:43:33' | System | 12 Apr 2021 16:43:41 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '10 Apr 2021 00:01' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '14 Apr 2021 23:59' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered 'Day 257' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[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 (e415f2ec5194138d)', Time: '2021-04-17T00:41:56-05:00', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'd308e8a9-1252-48c7-b131-7ae24059c9ad' | System | 17 Apr 2021 05:45:14 |
| User entered 'No (N)' | System | 17 Apr 2021 05:45:14 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

Have you been exposed to someone with 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 (e415f2ec5194138d)', Time: '2021-04-17T00:42:06-05:00', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'd308e8a9-1252-48c7-b131-7ae24059c9ad' | System | 17 Apr 2021 05:45:14 |
| User entered 'No (N)' | System | 17 Apr 2021 05:45:14 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e415f2ec5194138d)', Time: '2021-04-17T00:42:10-05:00', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'd308e8a9-1252-48c7-b131-7ae24059c9ad' | System | 17 Apr 2021 05:45:14 |
| User entered '17 Apr 2021 00:42:10' | System | 17 Apr 2021 05:45:14 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '17 Apr 2021 00:01' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '21 Apr 2021 23:59' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered 'Day 264' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[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 (e415f2ec5194138d)', Time: '2021-04-24T00:02:10-05:00', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '2b5f85d7-7f75-4f00-8e47-f83ec6150409' | System | 24 Apr 2021 05:02:47 |
| User entered 'No (N)' | System | 24 Apr 2021 05:02:47 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

Have you been exposed to someone with 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 (e415f2ec5194138d)', Time: '2021-04-24T00:02:18-05:00', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '2b5f85d7-7f75-4f00-8e47-f83ec6150409' | System | 24 Apr 2021 05:02:47 |
| User entered 'No (N)' | System | 24 Apr 2021 05:02:47 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e415f2ec5194138d)', Time: '2021-04-24T00:02:28-05:00', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '2b5f85d7-7f75-4f00-8e47-f83ec6150409' User entered '24 Apr 2021 00:02:28' | System | 24 Apr 2021 05:02:47 |
| | System | 24 Apr 2021 05:02:47 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '24 Apr 2021 00:01' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '28 Apr 2021 23:59' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered 'Day 271' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[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 (e415f2ec5194138d)', Time: '2021-05-01T07:11:42-05:00', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '98af001f-bb59-4c23-9495-ca9768a2ad68' | System | 01 May 2021 12:12:00 |
| User entered 'No (N)' | System | 01 May 2021 12:12:00 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

Have you been exposed to someone with 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 (e415f2ec5194138d)', Time: '2021-05-01T07:11:47-05:00', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '98af001f-bb59-4c23-9495-ca9768a2ad68' | System | 01 May 2021 12:12:00 |
| User entered 'No (N)' | System | 01 May 2021 12:12:00 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e415f2ec5194138d)', Time: '2021-05-01T07:11:56-05:00', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: '98af001f-bb59-4c23-9495-ca9768a2ad68' | System | 01 May 2021 12:12:00 |
| User entered '01 May 2021 07:11:56' | System | 01 May 2021 12:12:00 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '01 May 2021 00:01' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '05 May 2021 23:59' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered 'Day 278' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '08 May 2021 00:01' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '12 May 2021 23:59' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered 'Day 285' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '15 May 2021 00:01' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '19 May 2021 23:59' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered 'Day 292' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '22 May 2021 00:01' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '26 May 2021 23:59' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered 'Day 299' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '29 May 2021 00:01' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '02 Jun 2021 23:59' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered 'Day 306' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '05 Jun 2021 00:01' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '09 Jun 2021 23:59' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered 'Day 313' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '12 Jun 2021 00:01' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '16 Jun 2021 23:59' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered 'Day 320' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '19 Jun 2021 00:01' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '23 Jun 2021 23:59' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered 'Day 327' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '26 Jun 2021 00:01' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '30 Jun 2021 23:59' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered 'Day 334' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '03 Jul 2021 00:01' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '07 Jul 2021 23:59' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered 'Day 341' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '10 Jul 2021 00:01' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '14 Jul 2021 23:59' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered 'Day 348' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '17 Jul 2021 00:01' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '21 Jul 2021 23:59' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered 'Day 355' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '24 Jul 2021 00:01' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '28 Jul 2021 23:59' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered 'Day 362' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '31 Jul 2021 00:01' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '04 Aug 2021 23:59' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered 'Day 369' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '07 Aug 2021 00:01' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '11 Aug 2021 23:59' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered 'Day 376' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '14 Aug 2021 00:01' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '18 Aug 2021 23:59' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered 'Day 383' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '21 Aug 2021 00:01' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '25 Aug 2021 23:59' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered 'Day 390' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '28 Aug 2021 00:01' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '01 Sep 2021 23:59' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered 'Day 397' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '04 Sep 2021 00:01' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '08 Sep 2021 23:59' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered 'Day 404' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '11 Sep 2021 00:01' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '15 Sep 2021 23:59' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered 'Day 411' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '18 Sep 2021 00:01' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '22 Sep 2021 23:59' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered 'Day 418' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '25 Sep 2021 00:01' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '29 Sep 2021 23:59' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered 'Day 425' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '02 Oct 2021 00:01' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '06 Oct 2021 23:59' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered 'Day 432' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '09 Oct 2021 00:01' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '13 Oct 2021 23:59' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered 'Day 439' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '16 Oct 2021 00:01' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '20 Oct 2021 23:59' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered 'Day 446' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '23 Oct 2021 00:01' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '27 Oct 2021 23:59' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered 'Day 453' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '30 Oct 2021 00:01' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '03 Nov 2021 23:59' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered 'Day 460' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '06 Nov 2021 00:01' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '10 Nov 2021 23:59' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered 'Day 467' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '13 Nov 2021 00:01' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '17 Nov 2021 23:59' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered 'Day 474' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '20 Nov 2021 00:01' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '24 Nov 2021 23:59' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered 'Day 481' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '27 Nov 2021 00:01' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '01 Dec 2021 23:59' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered 'Day 488' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '04 Dec 2021 00:01' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '08 Dec 2021 23:59' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered 'Day 495' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '11 Dec 2021 00:01' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '15 Dec 2021 23:59' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered 'Day 502' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '18 Dec 2021 00:01' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '22 Dec 2021 23:59' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered 'Day 509' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '25 Dec 2021 00:01' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '29 Dec 2021 23:59' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered 'Day 516' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '01 Jan 2022 00:01' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '05 Jan 2022 23:59' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered 'Day 523' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '08 Jan 2022 00:01' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '12 Jan 2022 23:59' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered 'Day 530' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '15 Jan 2022 00:01' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '19 Jan 2022 23:59' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered 'Day 537' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '22 Jan 2022 00:01' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '26 Jan 2022 23:59' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered 'Day 544' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '29 Jan 2022 00:01' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '02 Feb 2022 23:59' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered 'Day 551' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '05 Feb 2022 00:01' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '09 Feb 2022 23:59' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered 'Day 558' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '12 Feb 2022 00:01' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '16 Feb 2022 23:59' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered 'Day 565' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '19 Feb 2022 00:01' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '23 Feb 2022 23:59' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered 'Day 572' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '26 Feb 2022 00:01' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '02 Mar 2022 23:59' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered 'Day 579' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '05 Mar 2022 00:01' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '09 Mar 2022 23:59' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered 'Day 586' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '12 Mar 2022 00:01' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '16 Mar 2022 23:59' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered 'Day 593' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '19 Mar 2022 00:01' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '23 Mar 2022 23:59' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered 'Day 600' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '26 Mar 2022 00:01' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '30 Mar 2022 23:59' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered 'Day 607' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '02 Apr 2022 00:01' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '06 Apr 2022 23:59' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered 'Day 614' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '09 Apr 2022 00:01' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '13 Apr 2022 23:59' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered 'Day 621' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '16 Apr 2022 00:01' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '20 Apr 2022 23:59' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered 'Day 628' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '23 Apr 2022 00:01' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '27 Apr 2022 23:59' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered 'Day 635' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '30 Apr 2022 00:01' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '04 May 2022 23:59' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered 'Day 642' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '07 May 2022 00:01' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '11 May 2022 23:59' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered 'Day 649' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '14 May 2022 00:01' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '18 May 2022 23:59' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered 'Day 656' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '21 May 2022 00:01' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '25 May 2022 23:59' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered 'Day 663' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '28 May 2022 00:01' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '01 Jun 2022 23:59' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered 'Day 670' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '04 Jun 2022 00:01' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '08 Jun 2022 23:59' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered 'Day 677' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '11 Jun 2022 00:01' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '15 Jun 2022 23:59' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered 'Day 684' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '18 Jun 2022 00:01' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '22 Jun 2022 23:59' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered 'Day 691' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '25 Jun 2022 00:01' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '29 Jun 2022 23:59' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered 'Day 698' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '02 Jul 2022 00:01' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '06 Jul 2022 23:59' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered 'Day 705' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '09 Jul 2022 00:01' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '13 Jul 2022 23:59' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered 'Day 712' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '16 Jul 2022 00:01' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '20 Jul 2022 23:59' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered 'Day 719' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '23 Jul 2022 00:01' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '27 Jul 2022 23:59' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered 'Day 726' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '30 Jul 2022 00:01' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '03 Aug 2022 23:59' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered 'Day 733' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '06 Aug 2022 00:01' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '10 Aug 2022 23:59' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered 'Day 740' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '13 Aug 2022 00:01' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '17 Aug 2022 23:59' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered 'Day 747' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '20 Aug 2022 00:01' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '24 Aug 2022 23:59' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered 'Day 754' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '27 Aug 2022 00:01' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '31 Aug 2022 23:59' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered 'Day 761' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '03 Sep 2022 00:01' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '07 Sep 2022 23:59' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered 'Day 768' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '10 Sep 2022 00:01' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '14 Sep 2022 23:59' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered 'Day 775' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '17 Sep 2022 00:01' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '21 Sep 2022 23:59' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered 'Day 782' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '24 Sep 2022 00:01' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '28 Sep 2022 23:59' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered 'Day 789' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '01 Oct 2022 00:01' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '05 Oct 2022 23:59' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered 'Day 796' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '08 Oct 2022 00:01' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:08

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 15:16:02 |
| Amendment Manager: User entered '12 Oct 2022 23:59' | System | 19 Nov 2020 15:16:02 |

US3062128

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:03:08

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:09:27 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e415f2ec5194138d)', Time: '2021-02-27T00:38:21-06:00', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'eaeaf83c-69f7-4a00-ac5d-e881662986ca' User entered 'No (N)' | System | 27 Feb 2021 06:38:26 |
| | System | 27 Feb 2021 06:38:26 |

US3062128

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:03:08

[Date & Time of Submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:09:27 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e415f2ec5194138d)', Time: '2021-02-27T00:38:24-06:00', User OID: 'PatientReportedOutcome (US3062128)', ODM File OID: 'eaeaf83c-69f7-4a00-ac5d-e881662986ca' User entered '27 Feb 2021 00:38:24' | System | 27 Feb 2021 06:38:26 |
| | System | 27 Feb 2021 06:38:26 |

US3062128

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:08

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Dec 2020 17:05:39 |
| User entered 'Yes (Y)' | Justin Phillips (b) (4) | 27 Oct 2020 22:37:34 |
| | (b) (4) | |

US3062128

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:08

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Dec 2020 17:05:39 |
| User entered '27 Oct 2020' | Justin Phillips (b) (4) | 27 Oct 2020 22:37:34 |
| | (b) (4) | |

US3062128

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:08

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Dec 2020 17:05:39 |
| User entered 'Contact Made (CONTACT MADE)' | Justin Phillips (b) (4) | 27 Oct 2020 22:37:34 |
| | (b) (4) | |

US3062128

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:08

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Dec 2020 17:05:39 |
| User entered empty. | Justin Phillips (b) (4) | 27 Oct 2020 22:37:34 |
| | (b) (4) | |

US3062128

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:08

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Dec 2020 17:05:45 |
| User entered 'Yes (Y)' | Justin Phillips (b) (4) | 27 Oct 2020 22:38:01 |
| | (b) (4) | |

US3062128

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:08

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:32:05 |
| User entered 'I' | System | 27 Oct 2020 22:38:01 |

US3062128

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:08

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 11:28:34 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 17 Mar 2021 18:59:34 |
| User entered 'Yes (Y)' | marissa Mueller (b) (4) | 15 Dec 2020 20:30:18 |
| | (b) (4) | |

US3062128

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:08

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 11:28:34 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 17 Mar 2021 18:59:34 |
| User entered '02 Dec 2020' | marissa Mueller (b) (4) | 15 Dec 2020 20:30:18 |
| | (b) (4) | |

US3062128

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:08

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 11:28:34 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 17 Mar 2021 18:59:34 |
| User entered 'Contact Made (CONTACT MADE)' | marissa Mueller (b) (4) | 15 Dec 2020 20:30:18 |
| | (b) (4) | |

US3062128

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:08

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 11:28:34 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 17 Mar 2021 18:59:34 |
| User entered empty. | marissa Mueller (b) (4) | 15 Dec 2020 20:30:18 |
| | (b) (4) | |

US3062128

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:08

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 11:28:34 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 17 Mar 2021 19:00:36 |
| User entered 'Yes (Y)' | marissa Mueller (b) (4) | 15 Dec 2020 20:30:29 |
| | (b) (4) | |

US3062128

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:08

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 11:28:34 |
| User entered 'I' | System | 15 Dec 2020 20:30:29 |

US3062128

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:08

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 11:28:34 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:58 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 16:55:46 |
| User entered 'Yes (Y)' | Riley King (b) (4) | 07 Jan 2021 22:32:29 |

US3062128

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:08

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 11:28:34 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:58 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 16:55:46 |
| User closed query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System). | (b) (4), (b) (6) | 12 Jan 2021 21:15:04 |
| Query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' answered with 'correct as entered' (Site from System). | Colton King (b) (4) | 11 Jan 2021 22:14:43 |
| User opened query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System). | System | 07 Jan 2021 22:32:29 |
| User entered '6 Jan 2021' | Riley King (b) (4) | 07 Jan 2021 22:32:29 |

US3062128

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:08

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 11:28:34 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:58 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 16:55:46 |
| User entered 'Contact Made (CONTACT MADE)' | Riley King (b) (4) | 07 Jan 2021 22:32:29 |

US3062128

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:08

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 11:28:34 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:58 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 16:55:46 |
| User entered empty. | Riley King (b) (4) | 07 Jan 2021 22:32:29 |
| | (b) (4) | |

US3062128

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:08

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 11:28:34 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:58 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 16:55:54 |
| User entered 'Yes (Y)' | Riley King (b) (4) | 07 Jan 2021 22:32:32 |
| | (b) (4) | |

US3062128

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:08

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 11:28:34 |
| User entered 'I' | System | 07 Jan 2021 22:32:32 |

US3062128

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:08

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 11:28:34 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:58 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:08:53 |
| User entered 'Yes (Y)' | Colton King (b) (4) | 04 Feb 2021 18:15:08 |
| | (b) (4) | |

US3062128

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:08

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 11:28:34 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:58 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:08:53 |
| User entered '3 Feb 2021' | Colton King (b) (4) | 04 Feb 2021 18:15:08 |
| | (b) (4) | |

US3062128

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:08

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 11:28:34 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:58 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:08:53 |
| User entered 'Contact Made (CONTACT MADE)' | Colton King (b) (4) | 04 Feb 2021 18:15:08 |

US3062128

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:08

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 11:28:34 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:58 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:08:53 |
| User entered empty. | Colton King (b) (4) | 04 Feb 2021 18:15:08 |
| | (b) (4) | |

US3062128

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:08

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 11:28:34 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:58 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:09:00 |
| User entered 'Yes (Y)' | Colton King (b) (4) | 04 Feb 2021 18:15:17 |

US3062128

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:08

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 11:28:34 |
| User entered 'I' | System | 04 Feb 2021 18:15:17 |

US3062128

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:03:08

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:11:07 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:58 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 17 Mar 2021 19:04:01 |
| User entered 'Yes (Y)' | Colton King (b) (4) | 19 Feb 2021 19:05:10 |
| | (b) (4) | |

US3062128

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:03:08

Visit date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:11:07 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:58 |
| DataPoint Verified. | (b) (4), (b) (6) | 17 Mar 2021 19:04:01 |
| User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 19FEB2021 is reported under Visit 4 Month 7 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under Visit 4 Day 209 Visit on Immunogenicity Assessment page.' (Site from DM). | (b) (4), (b) (6) | 12 Mar 2021 09:21:23 |
| Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 19FEB2021 is reported under Visit 4 Month 7 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under Visit 4 Day 209 Visit on Immunogenicity Assessment page.' answered with 'updated' (Site from DM). | marissa Mueller (b) (4) | 11 Mar 2021 19:28:49 |
| User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 19FEB2021 is reported under Visit 4 Month 7 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under Visit 4 Day 209 Visit on Immunogenicity Assessment page.' (Site from DM). | (b) (4), (b) (6) | 09 Mar 2021 11:14:33 |
| User entered '19 Feb 2021' | Colton King (b) (4) | 19 Feb 2021 19:05:10 |

US3062128

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:03:08

[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 18:11:07 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:58 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 17 Mar 2021 19:04:01 |
| User entered 'Clinic (Clinic)' | Colton King (b) (4) | 19 Feb 2021 19:05:10 |
| | (b) (4) | |

US3062128

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:03:08

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:11:07 |
| User entered 'VISIT4' | System | 19 Feb 2021 19:05:10 |

US3062128

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:08

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:11:07 |
| DataPoint Verified. | (b) (4), (b) (6) | 12 Apr 2021 13:45:24 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:58 |
| User entered 'Yes (Y)' | (b) (4) marissa Mueller (b) (4) | 01 Apr 2021 21:09:32 |
| | (b) (4) | |

US3062128

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:08

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:11:07 |
| DataPoint Verified. | (b) (4), (b) (6) | 12 Apr 2021 13:45:24 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:58 |
| User entered '19 Feb 2021' | (b) (4) marissa Mueller (b) (4) | 01 Apr 2021 21:09:32 |
| | (b) (4) | |

US3062128

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:11:07 |
| DataPoint Verified. | (b) (4), (b) (6) | 12 Apr 2021 13:45:24 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:58 |
| User entered '10:55' | (b) (4) marissa Mueller (b) (4) | 01 Apr 2021 21:09:32 |
| | (b) (4) | |

US3062128

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:11:07 |
| User entered '19 Feb 2021 10:55' | System | 01 Apr 2021 21:09:32 |

US3062128

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:08

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:11:07 |
| DataPoint Verified. | (b) (4), (b) (6) | 12 Apr 2021 13:45:24 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:58 |
| | (b) (4) | |
| User entered '97.7' F | marissa Mueller (b) (4) | 01 Apr 2021 21:09:32 |
| | (b) (4) | |

US3062128

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:08

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:11:07 |
| DataPoint Verified. | (b) (4), (b) (6) | 12 Apr 2021 13:45:24 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:58 |
| User entered 'Oral (Oral)' | (b) (4) marissa Mueller (b) (4) | 01 Apr 2021 21:09:32 |
| | (b) (4) | |

US3062128

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:08

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:11:07 |
| DataPoint Verified. | (b) (4), (b) (6) | 12 Apr 2021 13:45:24 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:58 |
| | (b) (4) | |
| User entered empty. | marissa Mueller (b) (4) | 01 Apr 2021 21:09:32 |
| | (b) (4) | |

US3062128

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:08

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:11:07 |
| DataPoint Verified. | (b) (4), (b) (6) | 12 Apr 2021 13:45:24 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:58 |
| | (b) (4) | |
| User entered '73' | marissa Mueller (b) (4) | 01 Apr 2021 21:09:32 |
| | (b) (4) | |

US3062128

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:08

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:11:07 |
| User entered 'bpm' | System | 01 Apr 2021 21:09:32 |

US3062128

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:11:07 |
| DataPoint Verified. | (b) (4), (b) (6) | 12 Apr 2021 13:45:24 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:58 |
| User entered '12' | (b) (4) marissa Mueller (b) (4) | 01 Apr 2021 21:09:32 |
| | (b) (4) | |

US3062128

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:08

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:11:07 |
| User entered 'breaths/min' | System | 01 Apr 2021 21:09:32 |

US3062128

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:08

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:11:07 |
| DataPoint Verified. | (b) (4), (b) (6) | 12 Apr 2021 13:45:24 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:58 |
| User entered '130' | (b) (4) marissa Mueller (b) (4) | 01 Apr 2021 21:09:32 |
| | (b) (4) | |

US3062128

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:08

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:11:07 |
| User entered 'mmHg' | System | 01 Apr 2021 21:09:32 |

US3062128

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:08

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:11:07 |
| DataPoint Verified. | (b) (4), (b) (6) | 12 Apr 2021 13:45:24 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:58 |
| | (b) (4) | |
| User entered '72' | marissa Mueller (b) (4) | 01 Apr 2021 21:09:32 |
| | (b) (4) | |

US3062128

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:08

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:11:07 |
| User entered 'mmHg' | System | 01 Apr 2021 21:09:32 |

US3062128

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:08

[Height \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:11:07 |
| | | |

US3062128

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:08

[Weight \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:11:07 |
| | | |

US3062128

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:03:08

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:11:07 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:58 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 17 Mar 2021 19:04:11 |
| User entered 'No (N)' | Colton King (b) (4) | 19 Feb 2021 19:05:35 |
| | (b) (4) | |

US3062128

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:03:08

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:11:07 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:58 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 17 Mar 2021 19:04:11 |
| User entered empty. | Colton King (b) (4) | 19 Feb 2021 19:05:35 |
| | (b) (4) | |

US3062128

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:03:08

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:11:07 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:58 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 17 Mar 2021 19:04:25 |
| User entered 'Yes (Y)' | marissa Mueller (b) (4) | 11 Mar 2021 19:29:00 |
| | (b) (4) | |

US3062128

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:03:08

Collection date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:11:07 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:58 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 17 Mar 2021 19:04:25 |
| User entered '19 Feb 2021' | marissa Mueller (b) (4) | 11 Mar 2021 19:29:00 |
| | (b) (4) | |

US3062128

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:03:08

[Collection time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:11:07 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:58 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 17 Mar 2021 19:04:25 |
| User entered '11:04' | marissa Mueller (b) (4) | 11 Mar 2021 19:29:00 |
| | (b) (4) | |

US3062128

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:03:08

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:11:07 |
| User entered '19 Feb 2021 11:04' | System | 11 Mar 2021 19:29:00 |

US3062128

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:08

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:11:07 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:58 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 17 Mar 2021 19:04:31 |
| User entered 'Yes (Y)' | Colton King (b) (4) | 19 Feb 2021 19:05:38 |
| | (b) (4) | |

US3062128

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:08

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:11:07 |
| User entered 'I' | System | 19 Feb 2021 19:05:38 |

US3062128

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:08

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 12 Apr 2021 13:46:22 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:58 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Colton King (b) (4) | 01 Apr 2021 20:09:03 |
| | (b) (4) | |

US3062128

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:08

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 12 Apr 2021 13:46:22 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:58 |
| | (b) (4) | |
| User entered '31 Mar 2021' | Colton King (b) (4) | 01 Apr 2021 20:09:03 |
| | (b) (4) | |

US3062128

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:08

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 12 Apr 2021 13:46:22 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:58 |
| | (b) (4) | |
| User entered 'Contact Made (CONTACT MADE)' | Colton King (b) (4) | 01 Apr 2021 20:09:03 |
| | (b) (4) | |

US3062128

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:08

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 12 Apr 2021 13:46:22 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:58 |
| User entered empty. | (b) (4) Colton King (b) (4) | 01 Apr 2021 20:09:03 |

US3062128

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:08

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 12 Apr 2021 13:46:29 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:58 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Colton King (b) (4) | 01 Apr 2021 20:08:50 |
| | (b) (4) | |

US3062128

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:08

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 01 Apr 2021 20:08:50 |

US3062128

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

Form: Visit Date

Generated On: 09 Jun 2021 15:03:08

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:02:16 |
| User entered 'Yes (Y)' | Colton King (b) (4) | 28 Jan 2021 20:21:19 |

US3062128

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

Form: Visit Date

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:02:16 |
| User entered '27 Jan 2021' | Colton King (b) (4) | 28 Jan 2021 20:21:19 |

US3062128

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

Form: Visit Date

Generated On: 09 Jun 2021 15:03:08

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

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:02:16 |
| User entered 'Clinic (Clinic)' | Colton King (b) (4) | 28 Jan 2021 20:21:19 |

US3062128

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

Form: Visit Date

Generated On: 09 Jun 2021 15:03:08

[Folder OID](#)

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User entered 'UNBLND_DECIDE' | System | 28 Jan 2021 20:21:19 |

US3062128

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

Form: Unblinding

Generated On: 09 Jun 2021 15:03:08

Date of updated informed consent (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:02:30 |
| User entered '27 Jan 2021' | Colton King (b) (4) | 28 Jan 2021 20:21:32 |

US3062128

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

Form: Unblinding

Generated On: 09 Jun 2021 15:03:08

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| User entered '0' WR# 5295537 | (b) (4) | 10 Mar 2021 16:55:28 |
| Amendment Manager inserted this DataPoint. | System | 06 Mar 2021 03:13:06 |

US3062128

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

Form: Unblinding

Generated On: 09 Jun 2021 15:03:08

[Was the participant unblinded?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:02:30 |
| User entered 'Yes (Y)' | Colton King (b) (4) | 28 Jan 2021 20:21:32 |

US3062128

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

Form: Unblinding

Generated On: 09 Jun 2021 15:03:08

[Under what version of the Protocol was the Participant unblinded?](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537 | (b) (4) | 10 Mar 2021 16:55:28 |
| Amendment Manager inserted this DataPoint. | System | 06 Mar 2021 03:13:06 |

US3062128

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

Form: Unblinding

Generated On: 09 Jun 2021 15:03:08

Date of unblinding (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:02:30 |
| User entered '27 Jan 2021' | Colton King (b) (4) | 28 Jan 2021 20:21:32 |

US3062128

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

Form: Unblinding

Generated On: 09 Jun 2021 15:03:08

[Participant randomization assignment](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:02:30 |
| User entered 'Placebo (Placebo)' | Colton King (b) (4) | 28 Jan 2021 20:21:32 |

US3062128

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

Form: Unblinding

Generated On: 09 Jun 2021 15:03:08

[Actual Dose 1](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:02:30 |
| User entered 'Placebo (Placebo)' | Colton King (b) (4) | 28 Jan 2021 20:21:32 |

US3062128

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

Form: Unblinding

Generated On: 09 Jun 2021 15:03:08

[Actual Dose 2](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:02:30 |
| User entered 'Placebo (Placebo)' | Colton King (b) (4) | 28 Jan 2021 20:21:32 |

US3062128

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

Form: Unblinding

Generated On: 09 Jun 2021 15:03:08

[Will participant receive mRNA-1273?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:02:30 |
| User entered 'Yes (Y)' | Colton King (b) (4) | 28 Jan 2021 20:21:32 |

US3062128

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

Form: Unblinding

Generated On: 09 Jun 2021 15:03:08

[Placebo Only Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User entered '1' | System | 28 Jan 2021 20:21:32 |

US3062128

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

Form: Unblinding

Generated On: 09 Jun 2021 15:03:08

[Continuing with mRNA-1273](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User entered 'I' | System | 28 Jan 2021 20:21:32 |

US3062128

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:03:08

[Height](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:03:28 |
| User entered '170.5' cm | Colton King (b) (4) | 28 Jan 2021 20:22:56 |

US3062128

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:03:08

[Weight](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:03:28 |
| User entered '76.5' kg | Colton King (b) (4) | 28 Jan 2021 20:22:56 |

US3062128

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:03:08

BMI (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User entered '26.31556' | System | 28 Jan 2021 20:22:56 |
| DataPoint set to visible. | System | 28 Jan 2021 20:21:32 |

US3062128

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:03:08

Height

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:03:28 |
| User entered '170.5' cm | Colton King (b) (4) | 28 Jan 2021 20:22:56 |

US3062128

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:03:08

[Weight](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:03:28 |
| User entered '76.5' kg | Colton King (b) (4) | 28 Jan 2021 20:22:56 |

US3062128

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:03:08

BMI (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User entered '26.31556' | System | 28 Jan 2021 20:22:56 |
| DataPoint set to visible. | System | 28 Jan 2021 20:21:32 |

US3062128

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:08

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User accepted default value 'Pre-Dose (PREDOSE)' | Colton King (b) (4) (b) (4) | 28 Jan 2021 20:22:56 |

US3062128

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:08

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:03:28 |
| User entered 'Yes (Y)' | Colton King (b) (4) | 28 Jan 2021 20:22:56 |

US3062128

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:08

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:03:28 |
| User entered '27 Jan 2021' | Colton King (b) (4) | 28 Jan 2021 20:22:56 |

US3062128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:08

Time of assessment (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:03:28 |
| User entered '09:35' | Colton King (b) (4) | 28 Jan 2021 20:22:56 |

US3062128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:08

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User entered '27 Jan 2021 09:35' | System | 28 Jan 2021 20:22:56 |

US3062128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:08

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:03:28 |
| User entered '97.4' F | Colton King (b) (4) | 28 Jan 2021 20:22:56 |

US3062128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:08

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:03:28 |
| User entered 'Oral (Oral)' | Colton King (b) (4) | 28 Jan 2021 20:22:56 |

US3062128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:08

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:03:28 |
| User entered empty. | Colton King (b) (4) | 28 Jan 2021 20:22:56 |

US3062128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:08

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:03:28 |
| User entered '75' | Colton King (b) (4) | 28 Jan 2021 20:22:56 |
| | (b) (4) | |

US3062128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:08

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User entered 'bpm' | System | 28 Jan 2021 20:22:56 |

US3062128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:08

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:03:28 |
| User entered '16' | Colton King (b) (4) | 28 Jan 2021 20:22:56 |

US3062128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:08

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User entered 'breaths/min' | System | 28 Jan 2021 20:22:56 |

US3062128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:08

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:03:28 |
| User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System). | System | 28 Jan 2021 20:23:41 |
| Query 'Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System). | System | 28 Jan 2021 20:23:41 |
| User entered '107' reason for change: Data Entry Error | Colton King (b) (4) | 28 Jan 2021 20:23:41 |
| User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System). | System | 28 Jan 2021 20:22:56 |
| User entered '707' | Colton King (b) (4) | 28 Jan 2021 20:22:56 |

US3062128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:08

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User entered 'mmHg' | System | 28 Jan 2021 20:22:56 |

US3062128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:08

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:03:28 |
| User entered '60' | Colton King (b) (4) | 28 Jan 2021 20:22:56 |

US3062128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:08

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User entered 'mmHg' | System | 28 Jan 2021 20:22:56 |

US3062128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:03:08

[Height](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:03:28 |
| User entered '170.5' cm | Colton King (b) (4) | 28 Jan 2021 20:22:56 |

US3062128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:03:08

[Weight](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:03:28 |
| User entered '76.5' kg | Colton King (b) (4) | 28 Jan 2021 20:22:56 |

US3062128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:03:08

BMI (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User entered '26.31556' | System | 28 Jan 2021 20:22:56 |
| DataPoint set to visible. | System | 28 Jan 2021 20:21:32 |

US3062128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:08

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User accepted default value 'Post-Dose (POSTDOSE)' | Colton King (b) (4) (b) (4) | 28 Jan 2021 20:22:56 |

US3062128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:08

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:03:28 |
| User entered 'Yes (Y)' | Colton King (b) (4) | 28 Jan 2021 20:22:56 |

US3062128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:08

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:03:28 |
| User entered '27 Jan 2021' | Colton King (b) (4) | 28 Jan 2021 20:22:56 |

US3062128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:08

Time of assessment (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:03:28 |
| User entered '11:15' | Colton King (b) (4) | 28 Jan 2021 20:22:56 |

US3062128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:08

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User entered '27 Jan 2021 11:15' | System | 28 Jan 2021 20:22:56 |

US3062128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:08

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:03:28 |
| User entered '97.6' F | Colton King (b) (4) | 28 Jan 2021 20:22:56 |

US3062128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:08

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:03:28 |
| User entered 'Oral (Oral)' | Colton King (b) (4) | 28 Jan 2021 20:22:56 |

US3062128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:08

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:03:28 |
| User entered empty. | Colton King (b) (4) | 28 Jan 2021 20:22:56 |

US3062128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:08

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:03:28 |
| User entered '71' | Colton King (b) (4) | 28 Jan 2021 20:22:56 |

US3062128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:08

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User entered 'bpm' | System | 28 Jan 2021 20:22:56 |

US3062128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:08

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:03:28 |
| User entered '16' | Colton King (b) (4) | 28 Jan 2021 20:22:56 |

US3062128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:08

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User entered 'breaths/min' | System | 28 Jan 2021 20:22:56 |

US3062128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:08

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:03:28 |
| User entered '137' | Colton King (b) (4) | 28 Jan 2021 20:22:56 |

US3062128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:08

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User entered 'mmHg' | System | 28 Jan 2021 20:22:56 |

US3062128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:08

[Diastolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:03:28 |
| User entered '73' | Colton King (b) (4) | 28 Jan 2021 20:22:56 |

US3062128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:08

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User entered 'mmHg' | System | 28 Jan 2021 20:22:56 |

US3062128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:03:08

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:03:39 |
| User entered 'Yes (Y)' | Colton King (b) (4) | 28 Jan 2021 20:24:09 |

US3062128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:03:08

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:03:39 |
| User entered '27 Jan 2021' | Colton King (b) (4) | 28 Jan 2021 20:24:09 |

US3062128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:03:08

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:04:08 |
| User entered 'Yes (Y)' | Colton King (b) (4) | 28 Jan 2021 20:24:22 |

US3062128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:03:08

[If No, reason not given](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:04:08 |
| User entered empty. | Colton King (b) (4) | 28 Jan 2021 20:24:22 |

US3062128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:03:08

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) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:04:08 |
| User entered empty. | Colton King (b) (4) | 28 Jan 2021 20:24:22 |

US3062128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:03:08

[What was the study treatment? \(Unblinded\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User entered 'mRNA-1273' | System | 28 Jan 2021 20:24:22 |
| DataPoint set to visible. | System | 28 Jan 2021 20:21:32 |

US3062128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:03:08

What was the treatment date? (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:04:08 |
| User entered '27 Jan 2021' | Colton King (b) (4) | 28 Jan 2021 20:24:22 |

US3062128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:03:08

[What was the treatment time? \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:04:08 |
| User entered '10:43' | Colton King (b) (4) | 28 Jan 2021 20:24:22 |

US3062128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:03:08

[Treatment Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User entered '27 Jan 2021 10:43' | System | 28 Jan 2021 20:24:22 |

US3062128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:03:08

[Which arm was used to give treatment?](#)

| Audit | User | Time (GMT) |
|------------------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:04:08 |
| User entered 'Left Arm (LEFT ARM)' | Colton King (b) (4) | 28 Jan 2021 20:24:22 |

US3062128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:03:08

[What was the frequency of the study treatment dosing?](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:04:08 |
| User entered 'ONCE' | System | 28 Jan 2021 20:24:22 |

US3062128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:03:08

What was the route of administration for the study treatment?

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User entered 'INTRAMUSCULAR' | System | 28 Jan 2021 20:24:22 |

US3062128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:03:08

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:05:31 |
| User entered 'Yes (Y)' | Colton King (b) (4) | 28 Jan 2021 20:24:34 |

US3062128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:03:08

Collection date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:05:31 |
| User entered '27 Jan 2021' | Colton King (b) (4) | 28 Jan 2021 20:24:34 |

US3062128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:03:08

Collection time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:05:31 |
| User entered '09:47' | Colton King (b) (4) | 28 Jan 2021 20:24:34 |

US3062128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:03:08

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User entered '27 Jan 2021 09:47' | System | 28 Jan 2021 20:24:34 |

US3062128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:03:08

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:05:38 |
| User entered 'Yes (Y)' | Colton King (b) (4) | 28 Jan 2021 20:24:46 |

US3062128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:03:08

Collection date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:05:38 |
| User entered '27 Jan 2021' | Colton King (b) (4) | 28 Jan 2021 20:24:46 |

US3062128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:03:08

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:05:38 |
| User entered '09:49' | Colton King (b) (4) | 28 Jan 2021 20:24:46 |

US3062128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:03:08

[Collection Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User entered '27 Jan 2021 09:49' | System | 28 Jan 2021 20:24:46 |

US3062128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:08

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:05:44 |
| User entered 'Yes (Y)' | Colton King (b) (4) | 28 Jan 2021 20:30:07 |

US3062128

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:08

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User entered '1' | System | 28 Jan 2021 20:30:07 |

US3062128

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:08

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:58 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:07:34 |
| User entered 'Yes (Y)' | Colton King (b) (4) | 05 Feb 2021 22:17:01 |

US3062128

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:08

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:58 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:07:34 |
| User entered '3 Feb 2021' | Colton King (b) (4) | 05 Feb 2021 22:17:01 |

US3062128

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:08

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:58 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:07:34 |
| User entered 'Contact Made (CONTACT MADE)' | Colton King (b) (4) | 05 Feb 2021 22:17:01 |

US3062128

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:08

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:58 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:07:34 |
| User entered empty. | Colton King (b) (4) | 05 Feb 2021 22:17:01 |

US3062128

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:08

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:58 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:07:49 |
| User entered 'Yes (Y)' | Colton King (b) (4) | 05 Feb 2021 22:17:12 |

US3062128

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:08

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User entered 'I' | System | 05 Feb 2021 22:17:12 |

US3062128

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:08

[OLD29 Placebo Flag](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User entered '1' | System | 05 Feb 2021 22:17:12 |
| DataPoint set to visible. | System | 05 Feb 2021 22:17:12 |

US3062128

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:03:08

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:10:57 |
| User entered 'Yes (Y)' | Colton King (b) (4) | 25 Feb 2021 20:49:04 |

US3062128

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:03:08

Visit date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:10:57 |
| User entered '24 Feb 2021' | Colton King (b) (4) | 25 Feb 2021 20:49:04 |

US3062128

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:03:08

[Was visit performed at the participant's home or at the clinic?](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:10:57 |
| User entered 'Clinic (Clinic)' | Colton King (b) (4) | 25 Feb 2021 20:49:04 |

US3062128

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:03:08

[Folder OID](#)

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User entered 'OLD29' | System | 25 Feb 2021 20:49:04 |

US3062128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:08

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User accepted default value 'Pre-Dose (PREDOSE)' | Colton King (b) (4) (b) (4) | 25 Feb 2021 21:06:14 |

US3062128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:08

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:13:49 |
| User entered 'Yes (Y)' | Colton King (b) (4) | 25 Feb 2021 21:06:14 |

US3062128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:08

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:13:49 |
| User entered '24 Feb 2021' | Colton King (b) (4) | 25 Feb 2021 21:06:14 |

US3062128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:08

Time of assessment (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:13:49 |
| User entered '12:24' | Colton King (b) (4) | 25 Feb 2021 21:06:14 |

US3062128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:08

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User entered '24 Feb 2021 12:24' | System | 25 Feb 2021 21:06:14 |

US3062128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:08

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:13:49 |
| User entered '97.8' F | Colton King (b) (4) | 25 Feb 2021 21:06:14 |

US3062128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:08

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:13:49 |
| User entered 'Oral (Oral)' | Colton King (b) (4) | 25 Feb 2021 21:06:14 |

US3062128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:08

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:13:49 |
| User entered empty. | Colton King (b) (4) | 25 Feb 2021 21:06:14 |

US3062128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:08

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:13:49 |
| User entered '83' | Colton King (b) (4) | 25 Feb 2021 21:06:14 |

US3062128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:08

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User entered 'bpm' | System | 25 Feb 2021 21:06:14 |

US3062128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:08

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:13:49 |
| User entered '16' | Colton King (b) (4) | 25 Feb 2021 21:06:14 |

US3062128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:08

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User entered 'breaths/min' | System | 25 Feb 2021 21:06:14 |

US3062128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:08

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:13:49 |
| User entered '106' | Colton King (b) (4) | 25 Feb 2021 21:06:14 |

US3062128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:08

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User entered 'mmHg' | System | 25 Feb 2021 21:06:14 |

US3062128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:08

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:13:49 |
| User entered '69' | Colton King (b) (4) | 25 Feb 2021 21:06:14 |

US3062128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:08

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User entered 'mmHg' | System | 25 Feb 2021 21:06:14 |

US3062128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:08

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User accepted default value 'Post-Dose (POSTDOSE)' | Colton King (b) (4) (b) (4) | 25 Feb 2021 21:06:14 |

US3062128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:08

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:13:49 |
| User entered 'Yes (Y)' | Colton King (b) (4) | 25 Feb 2021 21:06:14 |

US3062128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:08

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:13:49 |
| User entered '24 Feb 2021' | Colton King (b) (4) | 25 Feb 2021 21:06:14 |

US3062128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:08

Time of assessment (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:13:49 |
| User entered '13:40' | Colton King (b) (4) | 25 Feb 2021 21:06:14 |

US3062128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:08

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User entered '24 Feb 2021 13:40' | System | 25 Feb 2021 21:06:14 |

US3062128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:08

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:13:49 |
| User entered '98.4' F | Colton King (b) (4) | 25 Feb 2021 21:06:14 |

US3062128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:08

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:13:49 |
| User entered 'Oral (Oral)' | Colton King (b) (4) | 25 Feb 2021 21:06:14 |

US3062128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:08

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:13:49 |
| User entered empty. | Colton King (b) (4) | 25 Feb 2021 21:06:14 |

US3062128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:08

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:13:49 |
| User closed query 'Data is required. Please provide.' (Site from System). | System | 26 Feb 2021 14:52:05 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). | | 26 Feb 2021 14:52:05 |
| User entered '80' reason for change: Data Entry Error | Colton King (b) (4) | 26 Feb 2021 14:52:05 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 25 Feb 2021 21:06:14 |
| User entered empty. | Colton King (b) (4) | 25 Feb 2021 21:06:14 |

US3062128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:08

[Pulse units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User entered 'bpm' | System | 26 Feb 2021 14:52:05 |
| User entered empty. | System | 25 Feb 2021 21:06:14 |

US3062128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:08

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:13:49 |
| User entered '14' | Colton King (b) (4) | 25 Feb 2021 21:06:14 |

US3062128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:08

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User entered 'breaths/min' | System | 25 Feb 2021 21:06:14 |

US3062128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:08

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:13:49 |
| User closed query 'Data is required. Please provide.' (Site from System). | System | 26 Feb 2021 14:52:05 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). | | 26 Feb 2021 14:52:05 |
| User entered '111' reason for change: Data Entry Error | Colton King (b) (4) | 26 Feb 2021 14:52:05 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 25 Feb 2021 21:06:14 |
| User entered empty. | Colton King (b) (4) | 25 Feb 2021 21:06:14 |

US3062128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:08

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User entered 'mmHg' | System | 26 Feb 2021 14:52:05 |
| User entered empty. | System | 25 Feb 2021 21:06:14 |

US3062128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:08

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:13:49 |
| User closed query 'Data is required. Please provide.' (Site from System). | System | 26 Feb 2021 14:52:05 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). | | 26 Feb 2021 14:52:05 |
| User entered '71' reason for change: Data Entry Error | Colton King (b) (4) | 26 Feb 2021 14:52:05 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 25 Feb 2021 21:06:14 |
| User entered empty. | Colton King (b) (4) | 25 Feb 2021 21:06:14 |

US3062128

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:08

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User entered 'mmHg' | System | 26 Feb 2021 14:52:05 |
| User entered empty. | System | 25 Feb 2021 21:06:14 |

US3062128

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:03:08

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:13:01 |
| User entered 'Yes (Y)' | Colton King (b) (4) | 25 Feb 2021 21:06:44 |

US3062128

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:03:08

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:13:01 |
| User entered '24 Feb 2021' | Colton King (b) (4) | 25 Feb 2021 21:06:44 |

US3062128

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:03:08

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:15:10 |
| User entered 'Yes (Y)' | Colton King (b) (4) | 25 Feb 2021 21:07:19 |

US3062128

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:03:08

[If No, reason not given](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:15:10 |
| User entered empty. | Colton King (b) (4) | 25 Feb 2021 21:07:19 |

US3062128

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:03:08

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) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:15:10 |
| User entered empty. | Colton King (b) (4) | 25 Feb 2021 21:07:19 |

US3062128

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:03:08

[What was the study treatment? \(Unblinded\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User entered 'mRNA-1273' | System | 25 Feb 2021 21:07:19 |
| DataPoint set to visible. | System | 05 Feb 2021 22:17:12 |

US3062128

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:03:08

What was the treatment date? (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:15:10 |
| User entered '24 Feb 2021' | Colton King (b) (4) | 25 Feb 2021 21:07:19 |

US3062128

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:03:08

[What was the treatment time? \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:15:10 |
| User entered '13:09' | Colton King (b) (4) | 25 Feb 2021 21:07:19 |

US3062128

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:03:08

[Treatment Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User entered '24 Feb 2021 13:09' | System | 25 Feb 2021 21:07:19 |

US3062128

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:03:08

[Which arm was used to give treatment?](#)

| Audit | User | Time (GMT) |
|------------------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:15:10 |
| User entered 'Left Arm (LEFT ARM)' | Colton King (b) (4) | 25 Feb 2021 21:07:19 |

US3062128

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:03:08

[What was the frequency of the study treatment dosing?](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:15:10 |
| User entered 'ONCE' | System | 25 Feb 2021 21:07:19 |

US3062128

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:03:08

[What was the route of administration for the study treatment?](#)

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User entered 'INTRAMUSCULAR' | System | 25 Feb 2021 21:07:19 |

US3062128

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:08

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:15:18 |
| User entered 'Yes (Y)' | Colton King (b) (4) | 25 Feb 2021 21:07:24 |

US3062128

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:08

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User entered 'I' | System | 25 Feb 2021 21:07:24 |

US3062128

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:08

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:58 |
| DataPoint Verified. | (b) (4), (b) (6) | 17 Mar 2021 19:05:12 |
| User entered 'Yes (Y)' | Janna Martinez (b) (4) | 10 Mar 2021 15:55:37 |

US3062128

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:08

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:58 |
| DataPoint Verified. | (b) (4), (b) (6) | 17 Mar 2021 19:05:12 |
| User closed query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System). | (b) (4), (b) (6) | 15 Mar 2021 09:04:29 |
| Query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'deviation routing' (Site from System). | marissa Mueller (b) (4) | 11 Mar 2021 19:28:28 |
| User opened query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System). | System | 10 Mar 2021 15:55:37 |
| User entered '08 Mar 2021' | Janna Martinez (b) (4) | 10 Mar 2021 15:55:37 |

US3062128

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:08

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:58 |
| DataPoint Verified. | (b) (4), (b) (6) | 17 Mar 2021 19:05:12 |
| User entered 'Contact Made (CONTACT MADE)' | Janna Martinez (b) (4) | 10 Mar 2021 15:55:37 |

US3062128

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:08

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:58 |
| DataPoint Verified. | (b) (4), (b) (6) | 17 Mar 2021 19:05:12 |
| User entered empty. | Janna Martinez (b) (4) | 10 Mar 2021 15:55:37 |

US3062128

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:08

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:58 |
| DataPoint Verified. | (b) (4), (b) (6) | 17 Mar 2021 19:05:40 |
| User entered 'Yes (Y)' | Janna Martinez (b) (4) | 10 Mar 2021 15:56:14 |

US3062128

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:08

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User entered 'I' | System | 10 Mar 2021 15:56:14 |

US3062128

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:03:08

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 30 Mar 2021 19:52:55 |
| User entered 'Yes (Y)' | Colton King (b) (4) | 24 Mar 2021 20:40:06 |

US3062128

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:03:08

[Visit date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 30 Mar 2021 19:52:55 |
| User entered '24 Mar 2021' | Colton King (b) (4) | 24 Mar 2021 20:40:06 |

US3062128

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:03:08

[Was visit performed at the participant's home or at the clinic?](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 30 Mar 2021 19:52:55 |
| User entered 'Clinic (Clinic)' | Colton King (b) (4) | 24 Mar 2021 20:40:06 |

US3062128

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:03:08

[Folder OID](#)

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User entered 'OLD57' | System | 24 Mar 2021 20:40:06 |

US3062128

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:08

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 30 Mar 2021 19:54:17 |
| User entered 'Yes (Y)' | Colton King (b) (4) | 24 Mar 2021 20:40:55 |

US3062128

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:08

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 30 Mar 2021 19:54:17 |
| User entered '24 Mar 2021' | Colton King (b) (4) | 24 Mar 2021 20:40:55 |

US3062128

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:08

[Time of assessment \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 30 Mar 2021 19:54:17 |
| User entered '10:59' | Colton King (b) (4) | 24 Mar 2021 20:40:55 |

US3062128

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:08

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User entered '24 Mar 2021 10:59' | System | 24 Mar 2021 20:40:55 |

US3062128

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:08

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 30 Mar 2021 19:54:17 |
| User entered '97.9' F | Colton King (b) (4) | 24 Mar 2021 20:40:55 |

US3062128

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:08

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 30 Mar 2021 19:54:17 |
| User entered 'Oral (Oral)' | Colton King (b) (4) | 24 Mar 2021 20:40:55 |

US3062128

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:08

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 30 Mar 2021 19:54:17 |
| User entered empty. | Colton King (b) (4) | 24 Mar 2021 20:40:55 |

US3062128

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:08

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 30 Mar 2021 19:54:17 |
| User entered '84' | Colton King (b) (4) | 24 Mar 2021 20:40:55 |

US3062128

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:08

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User entered 'bpm' | System | 24 Mar 2021 20:40:55 |

US3062128

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:08

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 30 Mar 2021 19:54:17 |
| User entered '16' | Colton King (b) (4) | 24 Mar 2021 20:40:55 |

US3062128

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:08

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User entered 'breaths/min' | System | 24 Mar 2021 20:40:55 |

US3062128

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:08

[Systolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 30 Mar 2021 19:54:17 |
| User entered '117' | Colton King (b) (4) | 24 Mar 2021 20:40:55 |

US3062128

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:08

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User entered 'mmHg' | System | 24 Mar 2021 20:40:55 |

US3062128

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:08

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 30 Mar 2021 19:54:17 |
| User entered '77' | Colton King (b) (4) | 24 Mar 2021 20:40:55 |

US3062128

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:08

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User entered 'mmHg' | System | 24 Mar 2021 20:40:55 |

US3062128

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:08

[Height \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| | | |

US3062128

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:08

[Weight \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| | | |

US3062128

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:03:08

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 30 Mar 2021 19:54:31 |
| User entered 'No (N)' | Colton King (b) (4) | 24 Mar 2021 20:41:04 |

US3062128

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:03:08

Date of examination (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 30 Mar 2021 19:54:31 |
| User entered empty. | Colton King (b) (4) | 24 Mar 2021 20:41:04 |

US3062128

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:03:08

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 30 Mar 2021 19:54:44 |
| User entered 'Yes (Y)' | Colton King (b) (4) | 24 Mar 2021 20:41:27 |

US3062128

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:03:08

Collection date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 30 Mar 2021 19:54:44 |
| User entered '24 Mar 2021' | Colton King (b) (4) | 24 Mar 2021 20:41:27 |

US3062128

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:03:08

[Collection time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 30 Mar 2021 19:54:44 |
| User entered '11:07' | Colton King (b) (4) | 24 Mar 2021 20:41:27 |

US3062128

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:03:08

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:00:31 |
| User entered '24 Mar 2021 11:07' | System | 24 Mar 2021 20:41:27 |

US3062128

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:03:08

[Did the participant experience any adverse events?](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 07:16:40 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| User closed query 'please update with L sided body pain per AE log' (Site from CRA). | (b) (4), (b) (6) | 12 Mar 2021 22:02:45 |
| Query 'please update with L sided body pain per AE log' answered with 'no AE recorded for Left sided body pain' (Site from CRA). | marissa Mueller (b) (4) | 11 Mar 2021 19:29:58 |
| | (b) (4) | |
| User opened query 'please update with L sided body pain per AE log' (Site from CRA). | (b) (4), (b) (6) | 01 Mar 2021 17:43:50 |
| User closed query 'please update AE entry per AE log in source' (Site from CRA). | (b) (4), (b) (6) | 01 Feb 2021 22:39:06 |
| Query 'please update AE entry per AE log in source' answered with 'updated' (Site from CRA). | marissa Mueller (b) (4) | 22 Jan 2021 20:57:00 |
| | (b) (4) | |
| User opened query 'please update AE entry per AE log in source' (Site from CRA). | (b) (4), (b) (6) | 22 Jan 2021 16:27:26 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:33:58 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Jeri King (b) (4) | 09 Dec 2020 19:32:14 |
| User entered 'No (N)' | marissa Mueller (b) (4) | 01 Sep 2020 23:07:40 |
| | (b) (4) | |

US3062128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:08

[AEID](#)

| Audit | User | Time (GMT) |
|---------------------------------------|------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:42:26 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Dec 2020 21:11:25 |
| User entered | System | 10 Dec 2020 21:11:20 |
| 'USA-US090-2020-mRNA-1273-P301000010' | | |
| User entered 'New' | (b) (4), (b) (6) | 10 Dec 2020 21:11:20 |
| | | |

US3062128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:08

[Adverse event](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:42:26 |
| | | |
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Knee osteoarthritis - version MedDRA\\23.0. | Coder Import (b) (4) | 10 Dec 2020 14:07:59 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0. | Coder Import (b) (4) | 10 Dec 2020 14:07:59 |
| | (b) (4) | |
| Data point term sent to Coder | System | 09 Dec 2020 19:38:38 |
| User entered 'Worsening Osteoarthritis Right Knee' | Jeri King (b) (4) | 09 Dec 2020 19:38:24 |
| | | |

US3062128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:08

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:42:26 |
| | | |
| User entered 'Yes (Y)' | Jeri King (b) (4) | 09 Dec 2020 19:38:24 |
| | | |

US3062128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:08

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:42:26 |
| | | |
| User entered 'No (N)' | Jeri King (b) (4) | 09 Dec 2020 19:38:24 |
| | | |

US3062128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:08

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:42:26 |
| | | |
| User entered 'No (N)' | Jeri King (b) (4) | 09 Dec 2020 19:38:24 |
| | | |

US3062128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:08

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:42:26 |
| | | |
| User entered '03 Dec 2020' | Jeri King (b) (4) | 09 Dec 2020 19:38:24 |
| | | |

US3062128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:08

Start time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:42:26 |
| | | |
| User entered empty. | Jeri King (b) (4) | 09 Dec 2020 19:38:24 |
| | | |

US3062128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:08

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 09 Dec 2020 19:38:24 |

US3062128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:08

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:42:26 |
| | | |
| User entered 'No (N)' | Jeri King (b) (4) | 09 Dec 2020 19:38:24 |
| | | |

US3062128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:08

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:42:26 |
| | | |
| User entered '04 Dec 2020' | Jeri King (b) (4) | 09 Dec 2020 19:38:24 |
| | | |

US3062128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:08

End time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:42:26 |
| | | |
| User entered empty. | Jeri King (b) (4) | 09 Dec 2020 19:38:24 |
| | | |

US3062128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:08

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 09 Dec 2020 19:38:24 |

US3062128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:08

[Severity](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:42:26 |
| | | |
| User entered 'Grade 4 (Grade 4)' | Jeri King (b) (4) | 09 Dec 2020 19:38:24 |
| | | |

US3062128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:08

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:42:26 |
| | | |
| User entered 'Yes (Y)' | Jeri King (b) (4) | 09 Dec 2020 19:38:24 |
| | | |

US3062128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:08

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:42:26 |
| | | |
| User entered '0' | Jeri King (b) (4) | 09 Dec 2020 19:38:24 |
| | | |

US3062128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:08

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:42:26 |
| | | |
| User entered '0' | Jeri King (b) (4) | 09 Dec 2020 19:38:24 |
| | | |

US3062128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:08

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:42:26 |
| | | |
| User entered 'I' | Jeri King (b) (4) | 09 Dec 2020 19:38:24 |
| | | |

US3062128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:08

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:42:26 |
| | | |
| User entered '03 Dec 2020' | Jeri King (b) (4) | 09 Dec 2020 19:38:24 |
| | | |

US3062128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:08

Hospital Discharge Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:42:26 |
| | | |
| User entered '04 Dec 2020' | Jeri King (b) (4) | 09 Dec 2020 19:38:24 |
| | | |

US3062128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:08

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:42:26 |
| | | |
| User entered 'No (N)' | Jeri King (b) (4) | 09 Dec 2020 19:38:24 |
| | | |

US3062128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:08

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:42:26 |
| | | |
| User entered empty. | Jeri King (b) (4) | 09 Dec 2020 19:38:24 |
| | | |

US3062128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:08

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:42:26 |
| | | |
| User entered '0' | Jeri King (b) (4) | 09 Dec 2020 19:38:24 |
| | | |

US3062128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:08

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:42:26 |
| | | |
| User entered '0' | Jeri King (b) (4) | 09 Dec 2020 19:38:24 |
| | | |

US3062128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:08

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:42:26 |
| | | |
| User entered '0' | Jeri King (b) (4) | 09 Dec 2020 19:38:24 |
| | | |

US3062128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:08

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:42:26 |
| | | |
| User entered 'Not Related (NOT RELATED)' | Jeri King (b) (4) | 09 Dec 2020 19:38:24 |
| | | |

US3062128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:08

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:42:26 |
| User entered 'Not Related (NOT RELATED)' | Jeri King (b) (4) | 09 Dec 2020 19:38:24 |

US3062128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:08

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:42:26 |
| | | |
| User entered 'Not Applicable (NOT APPLICABLE)' | Jeri King (b) (4) | 09 Dec 2020 19:38:24 |
| | | |

US3062128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:08

None

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:42:26 |
| | | |
| User entered '0' | Jeri King (b) (4) | 09 Dec 2020 19:38:24 |
| | | |

US3062128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:08

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Feb 2021 22:32:53 |
| User closed query 'please add hospital meds once hosp records received' (Site from CRA). | (b) (4), (b) (6) | 01 Feb 2021 22:32:51 |
| Query 'please add hospital meds once hosp records received' answered with 'updated' (Site from CRA). | Riley King (b) (4) | 22 Dec 2020 21:36:04 |
| User entered '1' reason for change: Data Entry Error | (b) (4) | 22 Dec 2020 21:35:53 |
| User opened query 'please add hospital meds once hosp records received' (Site from CRA). | (b) (4), (b) (6) | 16 Dec 2020 15:43:24 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 16 Dec 2020 15:42:32 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:42:26 |
| User entered '0' | Jeri King (b) (4) | 09 Dec 2020 19:38:24 |

US3062128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:08

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:42:26 |
| | | |
| User entered 'I' | Jeri King (b) (4) | 09 Dec 2020 19:38:24 |
| | | |

US3062128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:08

[Outcome](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:42:26 |
| | | |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | Jeri King (b) (4) | 09 Dec 2020 19:38:24 |
| | | |

US3062128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:08

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:42:26 |
| | | |
| User entered empty. | Jeri King (b) (4) | 09 Dec 2020 19:38:24 |
| | | |

US3062128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:08

[Narrative](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Feb 2021 22:32:57 |
| User closed query 'PV Query: Please provide what caused (or precipitated) the worsening of the subject's osteoarthritis.' (Site from Safety). | (b) (4), (b) (6) | 14 Jan 2021 00:03:23 |
| 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) | 14 Jan 2021 00:03:15 |
| Query 'PV Query: Please provide what caused (or precipitated) the worsening of the subject's osteoarthritis.' answered with 'Natural progression of OA. ' (Site from Safety). | Riley King (b) (4) | 13 Jan 2021 16:03:07 |
| Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'N/A' (Site from Safety). | Riley King (b) (4) | 13 Jan 2021 16:00:04 |
| User closed query 'PV Query: Please confirm that the worsening of osteoarthritis occurred after study drug administration, and this was not a planned procedure prior to start of study drug. If this was a planned procedure prior to study drug administration, please consider deleting event as it does not meet reporting criteria.' (Site from Safety). | (b) (4), (b) (6) | 23 Dec 2020 15:15:02 |
| DataPoint Un-verified. | Riley King (b) (4) | 22 Dec 2020 21:38:47 |
| User entered 'SUBJECT WAS ADMITTED TO HOSPITAL FOR WORSENING OF RIGHT KNEE OSTEOARTHRITIS. SUBJECT UNDERWENT A RIGHT KNEE REPLACEMENT ON 12/3/2020. SUBJECT WAS DISCHARGED FROM THE HOSPITAL IN STABLE CONDITION ON 12/4/2020 TO HER OWN HOME. RELEASE OF RECORDS MAILED TO SUBJECT. Information from initial SAE remains unchanged and correct, follow up information gathered from medical records received includes additional AEs and conmeds.' reason for change: New Information | Riley King (b) (4) | 22 Dec 2020 21:38:47 |

US3062128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:08

[Narrative](#)

| Audit | User | Time (GMT) |
|--|-------------------------------|----------------------|
| Query 'PV Query: Please confirm that the worsening of osteoarthritis occurred after study drug administration, and this was not a planned procedure prior to start of study drug. If this was a planned procedure prior to study drug administration, please consider deleting event as it does not meet reporting criteria.' answered with 'was not planned prior to study start' (Site from Safety). | Riley King (b) (4) (b) (4) | 22 Dec 2020 21:36:13 |
| User opened query 'PV Query: Please provide what caused (or precipitated) the worsening of the subject's osteoarthritis.' (Site from Safety). | (b) (4), (b) (6) | 16 Dec 2020 17:10:35 |
| User opened query 'PV Query: Please confirm that the worsening of osteoarthritis occurred after study drug administration, and this was not a planned procedure prior to start of study drug. If this was a planned procedure prior to study drug administration, please consider deleting event as it does not meet reporting criteria.' (Site from Safety). | (b) (4), (b) (6) | 16 Dec 2020 17:10:01 |
| 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) | 16 Dec 2020 17:09:35 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:42:26 |
| User entered 'Subject was admitted to hospital for worsening of right knee osteoarthritis. Subject underwent a right knee replacement on 12/3/2020. Subject was discharged from the hospital in stable condition on 12/4/2020 to her own home. Release of records mailed to subject.' | Jeri King (b) (4) | 09 Dec 2020 19:38:24 |

US3062128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:08

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 09 Dec 2020 19:38:24 |

US3062128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:08

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 09 Dec 2020 19:38:24 |

US3062128

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:03:08

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '0' | System | 09 Dec 2020 19:38:24 |

US3062128

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:08

[AEID](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:07 |

US3062128

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:08

[Adverse event](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:07 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 16 Dec 2020 15:42:26 |
| User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Procedural related injuries and complications NEC, HLT: Non-site specific procedural complications, PT: Procedural pain, LLT: Postoperative pain - version MedDRA\\23.0. | Coder Import (b) (4) | 09 Dec 2020 19:41:11 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | (b) (4) | |
| Data point term sent to Coder | System | 09 Dec 2020 19:39:39 |
| User entered 'Postoperative pain' | Jeri King (b) (4) | 09 Dec 2020 19:39:11 |

US3062128

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:08

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:07 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:42:26 |
| User entered 'Yes (Y)' | Jeri King (b) (4) | 09 Dec 2020 19:39:11 |

US3062128

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:08

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:07 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:42:26 |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 09 Dec 2020 19:39:25 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 09 Dec 2020 19:39:25 |
| User entered 'No (N)' reason for change: Data Entry Error | Jeri King (b) (4) | 09 Dec 2020 19:39:25 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 09 Dec 2020 19:39:11 |
| User entered empty. | Jeri King (b) (4) | 09 Dec 2020 19:39:11 |

US3062128

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:08

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:07 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:42:26 |
| User entered 'No (N)' | Jeri King (b) (4) | 09 Dec 2020 19:39:11 |

US3062128

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:08

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:07 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:42:26 |
| User entered '03 Dec 2020' | Jeri King (b) (4) | 09 Dec 2020 19:39:11 |

US3062128

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:08

[Start time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:07 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:42:26 |
| User entered empty. | Jeri King (b) (4) | 09 Dec 2020 19:39:11 |

US3062128

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:08

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:07 |
| User entered empty. | System | 09 Dec 2020 19:39:11 |

US3062128

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:08

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:07 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| DataPoint Un-verified. | Colton King (b) (4) | 21 Jan 2021 22:00:33 |
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4) | 21 Jan 2021 22:00:33 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:42:26 |
| User entered 'Yes (Y)' | Jeri King (b) (4) | 09 Dec 2020 19:39:11 |

US3062128

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:08

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:07 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| 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 | 21 Jan 2021 22:00:45 |
| 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 | 21 Jan 2021 22:00:45 |
| 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 | 21 Jan 2021 22:00:33 |
| DataPoint Un-verified. | Colton King (b) (4) | 21 Jan 2021 22:00:33 |
| User entered '1 Jan 2021' reason for change: Data Entry Error | Colton King (b) (4) | 21 Jan 2021 22:00:33 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:42:26 |
| User entered empty. | Jeri King (b) (4) | 09 Dec 2020 19:39:11 |

US3062128

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:08

End time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:07 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:42:26 |
| User entered empty. | Jeri King (b) (4) | 09 Dec 2020 19:39:11 |

US3062128

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:08

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:07 |
| User entered empty. | System | 09 Dec 2020 19:39:11 |

US3062128

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:08

[Severity](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:07 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:42:26 |
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' | Jeri King (b) (4) | 09 Dec 2020 19:39:11 |

US3062128

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:08

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:07 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:42:26 |
| User entered 'No (N)' | Jeri King (b) (4) | 09 Dec 2020 19:39:11 |

US3062128

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:08

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:07 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:42:26 |
| User entered '0' | Jeri King (b) (4) | 09 Dec 2020 19:39:11 |

US3062128

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:08

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:07 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:42:26 |
| User entered '0' | Jeri King (b) (4) | 09 Dec 2020 19:39:11 |

US3062128

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:08

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:07 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:42:26 |
| User entered '0' | Jeri King (b) (4) | 09 Dec 2020 19:39:11 |

US3062128

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:08

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:07 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:42:26 |
| User entered empty. | Jeri King (b) (4) | 09 Dec 2020 19:39:11 |

US3062128

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:08

Hospital Discharge Date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:07 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:42:26 |
| User entered empty. | Jeri King (b) (4) | 09 Dec 2020 19:39:11 |

US3062128

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:08

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:07 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:42:26 |
| User entered empty. | Jeri King (b) (4) | 09 Dec 2020 19:39:11 |

US3062128

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:08

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:07 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:42:26 |
| User entered empty. | Jeri King (b) (4) | 09 Dec 2020 19:39:11 |

US3062128

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:08

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:07 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:42:26 |
| User entered '0' | Jeri King (b) (4) | 09 Dec 2020 19:39:11 |

US3062128

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:08

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:07 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:42:26 |
| User entered '0' | Jeri King (b) (4) | 09 Dec 2020 19:39:11 |

US3062128

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:08

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:07 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:42:26 |
| User entered '0' | Jeri King (b) (4) | 09 Dec 2020 19:39:11 |

US3062128

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:08

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:07 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:42:26 |
| User entered 'Not Related (NOT RELATED)' | Jeri King (b) (4) | 09 Dec 2020 19:39:11 |

US3062128

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:08

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:07 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:42:26 |
| User entered 'Not Related (NOT RELATED)' | Jeri King (b) (4) | 09 Dec 2020 19:39:11 |

US3062128

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:08

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:07 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:42:26 |
| User entered 'Not Applicable (NOT APPLICABLE)' | Jeri King (b) (4) | 09 Dec 2020 19:39:11 |

US3062128

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:08

None

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:07 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:42:26 |
| User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System). | System | 09 Dec 2020 19:39:25 |
| User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System). | System | 09 Dec 2020 19:39:11 |
| User entered '0' | Jeri King (b) (4) | 09 Dec 2020 19:39:11 |

US3062128

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:08

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:07 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:42:26 |
| User entered '1' reason for change: Data Entry Error | Jeri King (b) (4) | 09 Dec 2020 19:39:25 |
| User entered '0' | Jeri King (b) (4) | 09 Dec 2020 19:39:11 |

US3062128

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:08

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:07 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:42:26 |
| User entered '0' | Jeri King (b) (4) | 09 Dec 2020 19:39:11 |

US3062128

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:08

[Outcome](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:07 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4) | 01 Mar 2021 17:20:54 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error | Colton King (b) (4) | 21 Jan 2021 22:00:45 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 16 Dec 2020 15:49:46 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:42:26 |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 09 Dec 2020 19:39:36 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 09 Dec 2020 19:39:36 |
| User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error | Jeri King (b) (4) | 09 Dec 2020 19:39:36 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 09 Dec 2020 19:39:11 |
| User entered empty. | Jeri King (b) (4) | 09 Dec 2020 19:39:11 |

US3062128

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:08

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 13:44:07 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:42:26 |
| User entered empty. | Jeri King (b) (4) | 09 Dec 2020 19:39:11 |

US3062128

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:08

[Narrative](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:07 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:42:26 |
| User entered empty. | Jeri King (b) (4) | 09 Dec 2020 19:39:11 |

US3062128

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:08

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:07 |
| User entered '0' | System | 09 Dec 2020 19:39:11 |

US3062128

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:08

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:07 |
| User entered '1' | System | 09 Dec 2020 19:39:11 |

US3062128

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:08

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:07 |

US3062128

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:08

[AEID](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:11 |

US3062128

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:08

[Adverse event](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:11 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 16 Dec 2020 15:42:26 |
| User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Urinary tract infections, PT: Cystitis, LLT: Bladder infection - version MedDRA\\23.0. | Coder Import (b) (4) | 09 Dec 2020 19:47:57 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | (b) (4) | |
| Data point term sent to Coder | System | 09 Dec 2020 19:46:45 |
| User entered 'Bladder Infection' | Jeri King (b) (4) | 09 Dec 2020 19:45:45 |

US3062128

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:08

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:11 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:42:26 |
| User entered 'Yes (Y)' | Jeri King (b) (4) | 09 Dec 2020 19:45:45 |

US3062128

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:08

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:11 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:42:26 |
| User entered 'No (N)' | Jeri King (b) (4) | 09 Dec 2020 19:45:45 |

US3062128

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:08

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:11 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:42:26 |
| User entered 'No (N)' | Jeri King (b) (4) | 09 Dec 2020 19:45:45 |

US3062128

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:08

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:11 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:42:26 |
| User entered '30 Nov 2020' | Jeri King (b) (4) | 09 Dec 2020 19:45:45 |

US3062128

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:08

[Start time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:11 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:42:26 |
| User entered empty. | Jeri King (b) (4) | 09 Dec 2020 19:45:45 |

US3062128

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:08

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:11 |
| User entered empty. | System | 09 Dec 2020 19:45:45 |

US3062128

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:08

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:11 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:42:26 |
| User entered 'No (N)' | Jeri King (b) (4) | 09 Dec 2020 19:45:45 |

US3062128

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:08

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:11 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:42:26 |
| User entered '03 Dec 2020' | Jeri King (b) (4) | 09 Dec 2020 19:45:45 |

US3062128

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:08

End time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:11 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:42:26 |
| User entered empty. | Jeri King (b) (4) | 09 Dec 2020 19:45:45 |

US3062128

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:08

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:11 |
| User entered empty. | System | 09 Dec 2020 19:45:45 |

US3062128

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:08

[Severity](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:11 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:42:26 |
| User entered 'Grade 1/Mild (Grade 1/Mild)' | Jeri King (b) (4) | 09 Dec 2020 19:45:45 |

US3062128

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:08

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:11 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:42:26 |
| User entered 'No (N)' | Jeri King (b) (4) | 09 Dec 2020 19:45:45 |

US3062128

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:08

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:11 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:42:26 |
| User entered '0' | Jeri King (b) (4) | 09 Dec 2020 19:45:45 |

US3062128

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:08

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:11 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:42:26 |
| User entered '0' | Jeri King (b) (4) | 09 Dec 2020 19:45:45 |

US3062128

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:08

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:11 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:42:26 |
| User entered '0' | Jeri King (b) (4) | 09 Dec 2020 19:45:45 |

US3062128

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:08

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:11 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:42:26 |
| User entered empty. | Jeri King (b) (4) | 09 Dec 2020 19:45:45 |

US3062128

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:08

Hospital Discharge Date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:11 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:42:26 |
| User entered empty. | Jeri King (b) (4) | 09 Dec 2020 19:45:45 |

US3062128

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:08

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:11 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:42:26 |
| User entered empty. | Jeri King (b) (4) | 09 Dec 2020 19:45:45 |

US3062128

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:08

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:11 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:42:26 |
| User entered empty. | Jeri King (b) (4) | 09 Dec 2020 19:45:45 |

US3062128

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:08

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:11 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:42:26 |
| User entered '0' | Jeri King (b) (4) | 09 Dec 2020 19:45:45 |

US3062128

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:08

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:11 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:42:26 |
| User entered '0' | Jeri King (b) (4) | 09 Dec 2020 19:45:45 |

US3062128

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:08

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:11 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4) Stephan Penn (b) (4) | 16 Dec 2020 15:42:26 |
| User entered '0' | (b) (4) Jeri King (b) (4) | 09 Dec 2020 19:45:45 |

US3062128

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:08

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:11 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:42:26 |
| User entered 'Not Related (NOT RELATED)' | Jeri King (b) (4) | 09 Dec 2020 19:45:45 |

US3062128

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:08

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:11 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:42:26 |
| User entered 'Not Related (NOT RELATED)' | Jeri King (b) (4) | 09 Dec 2020 19:45:45 |

US3062128

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:08

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:11 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:42:26 |
| User entered 'Not Applicable (NOT APPLICABLE)' | Jeri King (b) (4) | 09 Dec 2020 19:45:45 |

US3062128

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:08

None

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:11 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:42:26 |
| User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System). | System | 09 Dec 2020 19:45:56 |
| User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System). | System | 09 Dec 2020 19:45:45 |
| User entered '0' | Jeri King (b) (4) | 09 Dec 2020 19:45:45 |

US3062128

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:08

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:11 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:42:26 |
| User entered '1' reason for change: Data Entry Error | Jeri King (b) (4) | 09 Dec 2020 19:45:56 |
| User entered '0' | Jeri King (b) (4) | 09 Dec 2020 19:45:45 |

US3062128

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:08

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:11 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:42:26 |
| User entered '0' | Jeri King (b) (4) | 09 Dec 2020 19:45:45 |

US3062128

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:08

[Outcome](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:11 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:42:26 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | Jeri King (b) (4) | 09 Dec 2020 19:45:45 |

US3062128

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:08

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 13:44:11 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:42:26 |
| User entered empty. | Jeri King (b) (4) | 09 Dec 2020 19:45:45 |

US3062128

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:08

[Narrative](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:11 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:42:26 |
| User entered empty. | Jeri King (b) (4) | 09 Dec 2020 19:45:45 |

US3062128

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:08

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:11 |
| User entered '0' | System | 09 Dec 2020 19:45:45 |

US3062128

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:08

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:11 |
| User entered '1' | System | 09 Dec 2020 19:45:45 |

US3062128

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:03:08

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:11 |

US3062128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:08

[AEID](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:09 |

US3062128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:08

[Adverse event](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:09 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4) | 01 Mar 2021 17:18:13 |
| User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Procedural related injuries and complications NEC, HLT: Gastrointestinal and hepatobiliary procedural complications, PT: Post procedural constipation, LLT: Postoperative constipation - version MedDRA\\23.0. | Coder Import (b) (4) | 24 Jan 2021 18:45:53 |
| User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0. | (b) (4) | 24 Jan 2021 18:45:53 |
| Data point term sent to Coder | System | 22 Jan 2021 20:52:46 |
| User entered 'post op constipation' | marissa Mueller (b) (4) | 22 Jan 2021 20:52:40 |
| | (b) (4) | |

US3062128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:08

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:09 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:18:15 |
| User entered 'Yes (Y)' | marissa Mueller (b) (4) | 22 Jan 2021 20:52:40 |

US3062128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:08

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:09 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:18:17 |
| User entered 'No (N)' | marissa Mueller (b) (4) | 22 Jan 2021 20:52:40 |
| | (b) (4) | |

US3062128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:08

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:09 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:18:19 |
| User entered 'No (N)' | marissa Mueller (b) (4) | 22 Jan 2021 20:52:40 |

US3062128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:08

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:09 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:18:21 |
| User entered '03 Dec 2020' | marissa Mueller (b) (4) | 22 Jan 2021 20:52:40 |

US3062128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:08

[Start time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:09 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:18:30 |
| User entered empty. | marissa Mueller (b) (4) | 22 Jan 2021 20:52:40 |

US3062128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:08

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:09 |
| User entered empty. | System | 22 Jan 2021 20:52:40 |

US3062128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:08

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:09 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:18:36 |
| User entered 'No (N)' | marissa Mueller (b) (4) | 22 Jan 2021 20:52:40 |

US3062128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:08

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:09 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:18:33 |
| User entered '04 Dec 2020' | marissa Mueller (b) (4) | 22 Jan 2021 20:52:40 |

US3062128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:08

End time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:09 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:18:39 |
| User entered empty. | marissa Mueller (b) (4) | 22 Jan 2021 20:52:40 |

US3062128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:08

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:09 |
| User entered empty. | System | 22 Jan 2021 20:52:40 |

US3062128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:08

[Severity](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:09 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:18:46 |
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' | marissa Mueller (b) (4) | 22 Jan 2021 20:52:40 |

US3062128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:08

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:09 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:18:48 |
| User entered 'No (N)' | marissa Mueller (b) (4) | 22 Jan 2021 20:52:40 |

US3062128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:08

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:09 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:18:50 |
| User entered '0' | marissa Mueller (b) (4) | 22 Jan 2021 20:52:40 |

US3062128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:08

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:09 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 01 Mar 2021 17:18:53 |
| User entered '0' | marissa Mueller (b) (4) | 22 Jan 2021 20:52:40 |
| | (b) (4) | |

US3062128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:08

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:09 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:18:55 |
| User entered '0' | marissa Mueller (b) (4) | 22 Jan 2021 20:52:40 |

US3062128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:08

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:09 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:18:58 |
| User entered empty. | marissa Mueller (b) (4) | 22 Jan 2021 20:52:40 |

US3062128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:08

Hospital Discharge Date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:09 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:19:15 |
| User entered empty. | marissa Mueller (b) (4) | 22 Jan 2021 20:52:40 |

US3062128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:08

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:09 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:19:16 |
| User entered empty. | marissa Mueller (b) (4) | 22 Jan 2021 20:52:40 |

US3062128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:08

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:09 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:19:18 |
| User entered empty. | marissa Mueller (b) (4) | 22 Jan 2021 20:52:40 |

US3062128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:08

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:09 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:19:20 |
| User entered '0' | marissa Mueller (b) (4) | 22 Jan 2021 20:52:40 |

US3062128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:08

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:09 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:19:22 |
| User entered '0' | marissa Mueller (b) (4) | 22 Jan 2021 20:52:40 |

US3062128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:08

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:09 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:19:24 |
| User entered '0' | marissa Mueller (b) (4) | 22 Jan 2021 20:52:40 |

US3062128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:08

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:09 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:19:25 |
| User entered 'Not Related (NOT RELATED)' | marissa Mueller (b) (4) | 22 Jan 2021 20:52:40 |

US3062128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:08

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:09 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:19:27 |
| User entered 'Not Related (NOT RELATED)' | marissa Mueller (b) (4) | 22 Jan 2021 20:52:40 |

US3062128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:08

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:09 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:19:29 |
| User entered 'Not Applicable (NOT APPLICABLE)' | marissa Mueller (b) (4) | 22 Jan 2021 20:52:40 |

US3062128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:08

None

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:09 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 01 Mar 2021 17:19:32 |
| User entered '0' | marissa Mueller (b) (4) | 22 Jan 2021 20:52:40 |
| | (b) (4) | |

US3062128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:08

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:09 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:19:34 |
| | | |
| User entered 'l' | marissa Mueller (b) (4) | 22 Jan 2021 20:52:40 |
| | (b) (4) | |

US3062128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:08

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:09 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:19:36 |
| User entered '0' | marissa Mueller (b) (4) | 22 Jan 2021 20:52:40 |

US3062128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:08

[Outcome](#)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:09 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:19:38 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | marissa Mueller (b) (4) | 22 Jan 2021 20:52:40 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:08

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 13:44:09 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:19:40 |
| | | |
| User entered empty. | marissa Mueller (b) (4) | 22 Jan 2021 20:52:40 |
| | (b) (4) | |

US3062128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:08

[Narrative](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:09 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:19:42 |
| User entered empty. | marissa Mueller (b) (4) | 22 Jan 2021 20:52:40 |

US3062128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:08

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:09 |
| User entered '0' | System | 22 Jan 2021 20:52:40 |

US3062128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:08

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:09 |
| User entered '1' | System | 22 Jan 2021 20:52:40 |

US3062128

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:03:08

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:09 |

US3062128

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:08

[AEID](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:28 |

US3062128

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:08

[Adverse event](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:28 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4) | 01 Mar 2021 17:20:54 |
| User coded data point as SOC: Gastrointestinal disorders, HLGIT: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Nausea, LLT: Nausea - version MedDRA\\23.0. | Coder Import (b) (4) | 24 Jan 2021 18:43:53 |
| User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0. | Coder Import (b) (4) | 24 Jan 2021 18:43:53 |
| Data point term sent to Coder | System | 22 Jan 2021 20:53:47 |
| User entered 'nausea, recurrent' | marissa Mueller (b) (4) | 22 Jan 2021 20:53:18 |
| | (b) (4) | |

US3062128

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:08

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:28 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| User entered 'Yes (Y)' | marissa Mueller (b) (4) | 22 Jan 2021 20:53:18 |
| | (b) (4) | |

US3062128

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:08

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:28 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| User entered 'No (N)' | marissa Mueller (b) (4) | 22 Jan 2021 20:53:18 |

US3062128

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:08

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:28 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| User entered 'No (N)' | marissa Mueller (b) (4) | 22 Jan 2021 20:53:18 |

US3062128

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:08

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:28 |
| | | |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| | | |
| User entered '03 Dec 2020' | marissa Mueller (b) (4) | 22 Jan 2021 20:53:18 |
| | (b) (4) | |

US3062128

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:08

[Start time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:28 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| User entered empty. | marissa Mueller (b) (4) | 22 Jan 2021 20:53:18 |

US3062128

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:08

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:28 |
| | | |
| User entered empty. | System | 22 Jan 2021 20:53:18 |

US3062128

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:08

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:28 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| User entered 'No (N)' | marissa Mueller (b) (4) | 22 Jan 2021 20:53:18 |

US3062128

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:08

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:28 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| User entered '04 Dec 2020' | marissa Mueller (b) (4) | 22 Jan 2021 20:53:18 |
| | (b) (4) | |

US3062128

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:08

End time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:28 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| User entered empty. | marissa Mueller (b) (4) | 22 Jan 2021 20:53:18 |

US3062128

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:08

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:28 |
| User entered empty. | System | 22 Jan 2021 20:53:18 |

US3062128

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:08

[Severity](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:28 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' | marissa Mueller (b) (4) | 22 Jan 2021 20:53:18 |

US3062128

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:08

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:28 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| User entered 'No (N)' | marissa Mueller (b) (4) | 22 Jan 2021 20:53:18 |

US3062128

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:08

Death

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:28 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| User entered '0' | marissa Mueller (b) (4) | 22 Jan 2021 20:53:18 |

US3062128

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:08

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:28 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| User entered '0' | marissa Mueller (b) (4) | 22 Jan 2021 20:53:18 |

US3062128

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:08

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:28 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| User entered '0' | marissa Mueller (b) (4) | 22 Jan 2021 20:53:18 |

US3062128

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:08

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:28 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| User entered empty. | marissa Mueller (b) (4) | 22 Jan 2021 20:53:18 |
| | (b) (4) | |

US3062128

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:08

Hospital Discharge Date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:28 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| User entered empty. | marissa Mueller (b) (4) | 22 Jan 2021 20:53:18 |
| | (b) (4) | |

US3062128

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:08

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:28 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| User entered empty. | marissa Mueller (b) (4) | 22 Jan 2021 20:53:18 |

US3062128

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:08

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:28 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| User entered empty. | marissa Mueller (b) (4) | 22 Jan 2021 20:53:18 |

US3062128

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:08

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:28 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| | | |
| User entered '0' | marissa Mueller (b) (4) | 22 Jan 2021 20:53:18 |
| | (b) (4) | |

US3062128

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:08

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:28 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| User entered '0' | marissa Mueller (b) (4) | 22 Jan 2021 20:53:18 |

US3062128

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:08

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:28 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| User entered '0' | marissa Mueller (b) (4) | 22 Jan 2021 20:53:18 |

US3062128

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:08

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:28 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| User entered 'Not Related (NOT RELATED)' | marissa Mueller (b) (4) | 22 Jan 2021 20:53:18 |

US3062128

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:08

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:28 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| User entered 'Not Related (NOT RELATED)' | marissa Mueller (b) (4) | 22 Jan 2021 20:53:18 |
| | (b) (4) | |

US3062128

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:08

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:28 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| User entered 'Not Applicable (NOT APPLICABLE)' | marissa Mueller (b) (4) | 22 Jan 2021 20:53:18 |

US3062128

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:08

None

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:28 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| User entered '0' | marissa Mueller (b) (4) | 22 Jan 2021 20:53:18 |

US3062128

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:08

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:28 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| User entered 'l' | marissa Mueller (b) (4) | 22 Jan 2021 20:53:18 |

US3062128

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:08

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:28 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| User entered '0' | marissa Mueller (b) (4) | 22 Jan 2021 20:53:18 |

US3062128

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:08

[Outcome](#)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:28 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | marissa Mueller (b) (4) | 22 Jan 2021 20:53:18 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:08

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 13:44:28 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| User entered empty. | marissa Mueller (b) (4) | 22 Jan 2021 20:53:18 |

US3062128

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:08

[Narrative](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:28 |
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| User entered empty. | marissa Mueller (b) (4) | 22 Jan 2021 20:53:18 |

US3062128

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:08

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:28 |
| User entered '0' | System | 22 Jan 2021 20:53:18 |

US3062128

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:08

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:28 |
| User entered '1' | System | 22 Jan 2021 20:53:18 |

US3062128

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:03:08

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:44:28 |

US3062128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:08

[Adverse event](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| | | |
| User coded data point as SOC: Blood and lymphatic system disorders, HLG: Anaemias nonhaemolytic and marrow depression, HLT: Anaemias NEC, PT: Anaemia, LLT: Anemia - version MedDRA\\23.0. | Coder Import (b) (4) | 22 Jan 2021 20:56:05 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 22 Jan 2021 20:56:05 |
| | (b) (4) | |
| Data point term sent to Coder | System | 22 Jan 2021 20:54:52 |
| User entered 'anemia' | marissa Mueller (b) (4) | 22 Jan 2021 20:53:57 |
| | | |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:08

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| | | |
| User entered 'No (N)' | marissa Mueller (b) (4) | 22 Jan 2021 20:53:57 |
| | (b) (4) | |

US3062128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:08

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| | | |
| User entered 'No (N)' | marissa Mueller (b) (4) | 22 Jan 2021 20:53:57 |
| | (b) (4) | |

US3062128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:08

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| | | |
| User entered 'No (N)' | marissa Mueller (b) (4) | 22 Jan 2021 20:53:57 |
| | (b) (4) | |

US3062128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:08

Start date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| User entered '04 Dec 2020' | marissa Mueller (b) (4) | 22 Jan 2021 20:53:57 |
| | (b) (4) | |

US3062128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:08

Start time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| User entered empty. | marissa Mueller (b) (4) | 22 Jan 2021 20:53:57 |
| | (b) (4) | |

US3062128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:08

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 22 Jan 2021 20:53:57 |

US3062128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:08

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| | | |
| User entered 'Yes (Y)' | marissa Mueller (b) (4) | 22 Jan 2021 20:53:57 |
| | (b) (4) | |

US3062128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:08

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| | | |
| User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System). | System | 22 Jan 2021 20:55:02 |
| Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System). | System | 22 Jan 2021 20:55:02 |
| User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System). | System | 22 Jan 2021 20:53:57 |
| User entered empty. | marissa Mueller (b) (4) | 22 Jan 2021 20:53:57 |
| | (b) (4) | |

US3062128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:08

[End time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| | | |
| User entered empty. | marissa Mueller (b) (4) | 22 Jan 2021 20:53:57 |
| | (b) (4) | |

US3062128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:08

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 22 Jan 2021 20:53:57 |

US3062128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:08

[Severity](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| | | |
| User entered 'Grade 1/Mild (Grade 1/Mild)' | marissa Mueller (b) (4) | 22 Jan 2021 20:53:57 |
| | (b) (4) | |

US3062128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:08

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| User entered 'No (N)' | marissa Mueller (b) (4) | 22 Jan 2021 20:53:57 |
| | (b) (4) | |

US3062128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:08

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| User entered '0' | marissa Mueller (b) (4) | 22 Jan 2021 20:53:57 |
| | (b) (4) | |

US3062128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:08

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| User entered '0' | marissa Mueller (b) (4) | 22 Jan 2021 20:53:57 |
| | (b) (4) | |

US3062128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:08

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| User entered '0' | marissa Mueller (b) (4) | 22 Jan 2021 20:53:57 |
| | (b) (4) | |

US3062128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:08

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| User entered empty. | marissa Mueller (b) (4) | 22 Jan 2021 20:53:57 |
| | (b) (4) | |

US3062128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:08

Hospital Discharge Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| | | |
| User entered empty. | marissa Mueller (b) (4) | 22 Jan 2021 20:53:57 |
| | (b) (4) | |

US3062128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:08

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| User entered empty. | marissa Mueller (b) (4) | 22 Jan 2021 20:53:57 |
| | (b) (4) | |

US3062128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:08

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| User entered empty. | marissa Mueller (b) (4) | 22 Jan 2021 20:53:57 |
| | (b) (4) | |

US3062128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:08

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| User entered '0' | marissa Mueller (b) (4) | 22 Jan 2021 20:53:57 |
| | (b) (4) | |

US3062128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:08

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| | | |
| User entered '0' | marissa Mueller (b) (4) | 22 Jan 2021 20:53:57 |
| | (b) (4) | |

US3062128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:08

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| | | |
| User entered '0' | marissa Mueller (b) (4) | 22 Jan 2021 20:53:57 |
| | (b) (4) | |

US3062128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:08

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| | | |
| User entered 'Not Related (NOT RELATED)' | marissa Mueller (b) (4) | 22 Jan 2021 20:53:57 |
| | (b) (4) | |

US3062128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:08

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| | | |
| User entered 'Not Related (NOT RELATED)' | marissa Mueller (b) (4) | 22 Jan 2021 20:53:57 |
| | (b) (4) | |

US3062128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:08

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| | | |
| User entered 'Not Applicable (NOT APPLICABLE)' | marissa Mueller (b) (4) | 22 Jan 2021 20:53:57 |
| | (b) (4) | |

US3062128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:08

None

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| | | |
| User entered 'I' | marissa Mueller (b) (4) | 22 Jan 2021 20:53:57 |
| | (b) (4) | |

US3062128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:08

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| | | |
| User entered '0' | marissa Mueller (b) (4) | 22 Jan 2021 20:53:57 |
| | (b) (4) | |

US3062128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:08

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| | | |
| User entered '0' | marissa Mueller (b) (4) | 22 Jan 2021 20:53:57 |
| | (b) (4) | |

US3062128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:08

[Outcome](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| | | |
| User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error | marissa Mueller (b) (4) | 22 Jan 2021 20:55:02 |
| | (b) (4) | |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | marissa Mueller (b) (4) | 22 Jan 2021 20:53:57 |
| | (b) (4) | |

US3062128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:08

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| User entered empty. | marissa Mueller (b) (4) | 22 Jan 2021 20:53:57 |
| | (b) (4) | |

US3062128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:08

[Narrative](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| | | |
| User entered empty. | marissa Mueller (b) (4) | 22 Jan 2021 20:53:57 |
| | (b) (4) | |

US3062128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:08

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '0' | System | 22 Jan 2021 20:53:57 |

US3062128

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:03:08

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '0' | System | 22 Jan 2021 20:53:57 |

US3062128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:03:08

[Adverse event](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| | | |
| User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Sensory abnormalities NEC, PT: Restless legs syndrome, LLT: Restless leg syndrome - version MedDRA\\23.0. | Coder Import (b) (4) | 22 Jan 2021 20:57:06 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 22 Jan 2021 20:57:06 |
| | (b) (4) | |
| Data point term sent to Coder | System | 22 Jan 2021 20:55:52 |
| User entered 'restless leg syndrome' | marissa Mueller (b) (4) | 22 Jan 2021 20:55:39 |
| | | |
| | (b) (4) | |

US3062128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:03:08

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| | | |
| User entered 'No (N)' | marissa Mueller (b) (4) | 22 Jan 2021 20:55:39 |
| | (b) (4) | |

US3062128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:03:08

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| | | |
| User entered 'No (N)' | marissa Mueller (b) (4) | 22 Jan 2021 20:55:39 |
| | (b) (4) | |

US3062128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:03:08

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| | | |
| User entered 'No (N)' | marissa Mueller (b) (4) | 22 Jan 2021 20:55:39 |
| | (b) (4) | |

US3062128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:03:08

Start date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| User entered '02 Nov 2020' | marissa Mueller (b) (4) | 22 Jan 2021 20:55:39 |
| | (b) (4) | |

US3062128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:03:08

Start time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| User entered empty. | marissa Mueller (b) (4) | 22 Jan 2021 20:55:39 |
| | (b) (4) | |

US3062128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:03:08

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 22 Jan 2021 20:55:39 |

US3062128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:03:08

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| | | |
| User entered 'Yes (Y)' | marissa Mueller (b) (4) | 22 Jan 2021 20:55:39 |
| | (b) (4) | |

US3062128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:03:08

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| User entered empty. | marissa Mueller (b) (4) | 22 Jan 2021 20:55:39 |
| | (b) (4) | |

US3062128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:03:08

[End time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| User entered empty. | marissa Mueller (b) (4) | 22 Jan 2021 20:55:39 |
| | (b) (4) | |

US3062128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:03:08

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 22 Jan 2021 20:55:39 |

US3062128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:03:08

[Severity](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| User entered 'Grade 1/Mild (Grade 1/Mild)' | marissa Mueller (b) (4) | 22 Jan 2021 20:55:39 |
| | (b) (4) | |

US3062128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:03:08

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| | | |
| User entered 'No (N)' | marissa Mueller (b) (4) | 22 Jan 2021 20:55:39 |
| | (b) (4) | |

US3062128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:03:08

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| | | |
| User entered '0' | marissa Mueller (b) (4) | 22 Jan 2021 20:55:39 |
| | (b) (4) | |

US3062128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:03:08

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| | | |
| User entered '0' | marissa Mueller (b) (4) | 22 Jan 2021 20:55:39 |
| | (b) (4) | |

US3062128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:03:08

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| | | |
| User entered '0' | marissa Mueller (b) (4) | 22 Jan 2021 20:55:39 |
| | (b) (4) | |

US3062128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:03:08

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| User entered empty. | marissa Mueller (b) (4) | 22 Jan 2021 20:55:39 |
| | (b) (4) | |

US3062128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:03:08

Hospital Discharge Date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| | | |
| User entered empty. | marissa Mueller (b) (4) | 22 Jan 2021 20:55:39 |
| | (b) (4) | |

US3062128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:03:08

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| | | |
| User entered empty. | marissa Mueller (b) (4) | 22 Jan 2021 20:55:39 |
| | (b) (4) | |
| | (b) (4) | |

US3062128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:03:08

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| User entered empty. | marissa Mueller (b) (4) | 22 Jan 2021 20:55:39 |
| | (b) (4) | |

US3062128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:03:08

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| User entered '0' | marissa Mueller (b) (4) | 22 Jan 2021 20:55:39 |
| | (b) (4) | |

US3062128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:03:08

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| | | |
| User entered '0' | marissa Mueller (b) (4) | 22 Jan 2021 20:55:39 |
| | (b) (4) | |

US3062128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:03:08

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| User entered '0' | marissa Mueller (b) (4) | 22 Jan 2021 20:55:39 |
| | (b) (4) | |

US3062128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:03:08

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| | | |
| User entered 'Not Related (NOT RELATED)' | marissa Mueller (b) (4) | 22 Jan 2021 20:55:39 |
| | (b) (4) | |

US3062128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:03:08

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| | | |
| User entered 'Not Related (NOT RELATED)' | marissa Mueller (b) (4) | 22 Jan 2021 20:55:39 |
| | (b) (4) | |

US3062128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:03:08

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| | | |
| User entered 'Not Applicable (NOT APPLICABLE)' | marissa Mueller (b) (4) | 22 Jan 2021 20:55:39 |
| | (b) (4) | |

US3062128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:03:08

None

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| | | |
| User entered 'I' | marissa Mueller (b) (4) | 22 Jan 2021 20:55:39 |
| | (b) (4) | |

US3062128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:03:08

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| | | |
| User entered '0' | marissa Mueller (b) (4) | 22 Jan 2021 20:55:39 |
| | (b) (4) | |

US3062128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:03:08

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| | | |
| User entered '0' | marissa Mueller (b) (4) | 22 Jan 2021 20:55:39 |
| | (b) (4) | |

US3062128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:03:08

[Outcome](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| | | |
| User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' | marissa Mueller (b) (4) | 22 Jan 2021 20:55:39 |
| | (b) (4) | |

US3062128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:03:08

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| User entered empty. | marissa Mueller (b) (4) | 22 Jan 2021 20:55:39 |
| | (b) (4) | |

US3062128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:03:08

[Narrative](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| | | |
| User entered empty. | marissa Mueller (b) (4) | 22 Jan 2021 20:55:39 |
| | (b) (4) | |

US3062128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:03:08

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '0' | System | 22 Jan 2021 20:55:39 |

US3062128

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:03:08

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '0' | System | 22 Jan 2021 20:55:39 |

US3062128

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:03:08

[Adverse event](#)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| | | |
| User coded data point as SOC: Renal and urinary disorders, HLGT: Bladder and bladder neck disorders (excl calculi), HLT: Bladder infections and inflammations, PT: Cystitis interstitial, LLT: Cystitis interstitial - version MedDRA\\23.0. | Coder Import (b) (4) | 22 Feb 2021 18:19:03 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 22 Feb 2021 18:19:03 |
| | (b) (4) | |
| Data point term sent to Coder | System | 22 Feb 2021 18:18:13 |
| Coding entries removed. | Cayla Lawless (b) (4) | 22 Feb 2021 18:17:14 |
| | | |
| | (b) (4) | |
| User entered 'Interstitial Cystitis' reason for change: New Information | Cayla Lawless (b) (4) | 22 Feb 2021 18:17:14 |
| | | |
| | (b) (4) | |
| Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' canceled (Site from DM). | (b) (4), (b) (6) | 15 Feb 2021 02:01:41 |
| | | |
| User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM). | (b) (4), (b) (6) | 15 Feb 2021 02:01:28 |
| | | |
| User coded data point as SOC: Renal and urinary disorders, HLGT: Urinary tract signs and symptoms, HLT: Bladder and urethral symptoms, PT: Dysuria, LLT: Dysuria - version MedDRA\\23.0. | Coder Import (b) (4) | 22 Jan 2021 20:58:05 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 22 Jan 2021 20:58:05 |
| | (b) (4) | |
| Data point term sent to Coder | System | 22 Jan 2021 20:56:53 |
| User entered 'dysuria' | marissa Mueller (b) (4) | 22 Jan 2021 20:56:38 |
| | | |
| | (b) (4) | |

US3062128

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:03:08

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| | | |
| User entered 'No (N)' | marissa Mueller (b) (4) | 22 Jan 2021 20:56:38 |
| | (b) (4) | |

US3062128

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:03:08

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| | | |
| User entered 'No (N)' | marissa Mueller (b) (4) | 22 Jan 2021 20:56:38 |
| | (b) (4) | |

US3062128

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:03:08

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| | | |
| User entered 'No (N)' | marissa Mueller (b) (4) | 22 Jan 2021 20:56:38 |
| | (b) (4) | |

US3062128

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:03:08

Start date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| User entered '12 Nov 2020' | marissa Mueller (b) (4) | 22 Jan 2021 20:56:38 |
| | (b) (4) | |

US3062128

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:03:08

[Start time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| User entered empty. | marissa Mueller (b) (4) | 22 Jan 2021 20:56:38 |
| | (b) (4) | |

US3062128

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:03:08

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 22 Jan 2021 20:56:38 |

US3062128

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:03:08

[Ongoing?](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| | (b) (4), (b) (6) | |
| User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM). | | 24 Feb 2021 09:31:35 |
| Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' answered with 'Information updated per source. ' (Site from DM). | Cayla Lawless (b) (4) | 22 Feb 2021 18:17:46 |
| | (b) (4) | |
| User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM). | (b) (4), (b) (6) | 15 Feb 2021 02:01:47 |
| | | |
| User entered 'Yes (Y)' | marissa Mueller (b) (4) | 22 Jan 2021 20:56:38 |
| | (b) (4) | |

US3062128

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:03:08

If not Ongoing, end date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| | | |
| User entered empty. | marissa Mueller (b) (4) | 22 Jan 2021 20:56:38 |
| | (b) (4) | |

US3062128

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:03:08

End time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| User entered empty. | marissa Mueller (b) (4) | 22 Jan 2021 20:56:38 |
| | (b) (4) | |

US3062128

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:03:08

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 22 Jan 2021 20:56:38 |

US3062128

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:03:08

[Severity](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| User entered 'Grade 1/Mild (Grade 1/Mild)' | marissa Mueller (b) (4) | 22 Jan 2021 20:56:38 |
| | (b) (4) | |

US3062128

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:03:08

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| | | |
| User entered 'No (N)' | marissa Mueller (b) (4) | 22 Jan 2021 20:56:38 |
| | (b) (4) | |

US3062128

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:03:08

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| | | |
| User entered '0' | marissa Mueller (b) (4) | 22 Jan 2021 20:56:38 |
| | (b) (4) | |

US3062128

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:03:08

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| User entered '0' | marissa Mueller (b) (4) | 22 Jan 2021 20:56:38 |
| | (b) (4) | |

US3062128

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:03:08

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| User entered '0' | marissa Mueller (b) (4) | 22 Jan 2021 20:56:38 |
| | (b) (4) | |

US3062128

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:03:08

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| | | |
| User entered empty. | marissa Mueller (b) (4) | 22 Jan 2021 20:56:38 |
| | (b) (4) | |

US3062128

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:03:08

Hospital Discharge Date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| | | |
| User entered empty. | marissa Mueller (b) (4) | 22 Jan 2021 20:56:38 |
| | (b) (4) | |

US3062128

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:03:08

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| User entered empty. | marissa Mueller (b) (4) | 22 Jan 2021 20:56:38 |
| | (b) (4) | |

US3062128

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:03:08

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| User entered empty. | marissa Mueller (b) (4) | 22 Jan 2021 20:56:38 |
| | (b) (4) | |

US3062128

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:03:08

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| User entered '0' | marissa Mueller (b) (4) | 22 Jan 2021 20:56:38 |
| | (b) (4) | |

US3062128

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:03:08

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| | | |
| User entered '0' | marissa Mueller (b) (4) | 22 Jan 2021 20:56:38 |
| | (b) (4) | |

US3062128

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:03:08

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| | | |
| User entered '0' | marissa Mueller (b) (4) | 22 Jan 2021 20:56:38 |
| | (b) (4) | |

US3062128

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:03:08

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| | | |
| User entered 'Not Related (NOT RELATED)' | marissa Mueller (b) (4) | 22 Jan 2021 20:56:38 |
| | (b) (4) | |

US3062128

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:03:08

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| | | |
| User entered 'Not Related (NOT RELATED)' | marissa Mueller (b) (4) | 22 Jan 2021 20:56:38 |
| | (b) (4) | |

US3062128

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:03:08

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| | | |
| User entered 'Not Applicable (NOT APPLICABLE)' | marissa Mueller (b) (4) | 22 Jan 2021 20:56:38 |
| | (b) (4) | |

US3062128

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:03:08

None

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| | | |
| User entered 'I' | marissa Mueller (b) (4) | 22 Jan 2021 20:56:38 |
| | (b) (4) | |

US3062128

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:03:08

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| | | |
| User entered '0' | marissa Mueller (b) (4) | 22 Jan 2021 20:56:38 |
| | (b) (4) | |

US3062128

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:03:08

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| | | |
| User entered '0' | marissa Mueller (b) (4) | 22 Jan 2021 20:56:38 |
| | (b) (4) | |

US3062128

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:03:08

[Outcome](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| | | |
| User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' | marissa Mueller (b) (4) | 22 Jan 2021 20:56:38 |
| | (b) (4) | |

US3062128

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:03:08

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| User entered empty. | marissa Mueller (b) (4) | 22 Jan 2021 20:56:38 |
| | (b) (4) | |

US3062128

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:03:08

[Narrative](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Richard Glover (b) (4) | 31 Mar 2021 20:58:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:20:54 |
| | | |
| User entered empty. | marissa Mueller (b) (4) | 22 Jan 2021 20:56:38 |
| | (b) (4) | |

US3062128

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:03:08

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '0' | System | 22 Jan 2021 20:56:38 |

US3062128

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:03:08

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '0' | System | 22 Jan 2021 20:56:38 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:03:08

Were any prior/concomitant medications and/or vaccinations taken?

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 07:16:40 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| User closed query 'please add tetanus vaccine 17Feb per ePIP in source to CM log in eCRF and source' (Site from CRA). | (b) (4), (b) (6) | 17 Mar 2021 19:17:41 |
| User closed query 'please add amitriptyline 25mg 25Nov for interstitial cystitis per CM log' (Site from CRA). | (b) (4), (b) (6) | 12 Mar 2021 22:11:05 |
| Query 'please add tetanus vaccine 17Feb per ePIP in source to CM log in eCRF and source' answered with 'PLEASE PROVIDE AN ePIP NUMBER AS THERE IS NO ePIP DOCUMENTED AT THE SITE LEVEL FOR THIS SUBJECT.' (Site from CRA). | Janna Martinez (b) (4) | 10 Mar 2021 16:27:09 |
| | (b) (4) | |
| Query 'please add amitriptyline 25mg 25Nov for interstitial cystitis per CM log' answered with 'DATA CORRECTED' (Site from CRA). | Janna Martinez (b) (4) | 10 Mar 2021 16:02:57 |
| | (b) (4) | |
| User opened query 'please add tetanus vaccine 17Feb per ePIP in source to CM log in eCRF and source' (Site from CRA). | (b) (4), (b) (6) | 01 Mar 2021 17:42:03 |
| User opened query 'please add amitriptyline 25mg 25Nov for interstitial cystitis per CM log' (Site from CRA). | (b) (4), (b) (6) | 01 Mar 2021 17:28:11 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 14:56:56 |
| User entered 'Yes (Y)' | Janna Martinez (b) (4) | 07 Aug 2020 22:56:02 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:03:08

Name of Medication

| Audit | User | Time (GMT) |
|---|---|--|
| User signature succeeded. | Troy Holdeman (b) (4) (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| 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: IBANDRONATE SODIUM, PRODUCTSYNONYM: BONIVA - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 07 Aug 2020 22:59:24 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 07 Aug 2020 22:59:24 |
| Data point term sent to Coder User entered 'BONIVA' | System Janna Martinez (b) (4) (b) (4) | 07 Aug 2020 22:57:52 07 Aug 2020 22:57:12 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:03:08

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered 'No (N)' | Janna Martinez (b) (4) | 07 Aug 2020 22:57:12 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:03:08

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered 'OSTEOPENIA' | Janna Martinez (b) (4) | 07 Aug 2020 22:57:12 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:03:08

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered '150' | Janna Martinez (b) (4) | 07 Aug 2020 22:57:12 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:03:08

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered 'mg (mg)' | Janna Martinez (b) (4) | 07 Aug 2020 22:57:12 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:03:08

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered empty. | Janna Martinez (b) (4) | 07 Aug 2020 22:57:12 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:03:08

[Frequency](#)

| Audit | User | Time (GMT) |
|---------------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered 'every month (QM)' | Janna Martinez (b) (4) | 07 Aug 2020 22:57:12 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:03:08

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered empty. | Janna Martinez (b) (4) | 07 Aug 2020 22:57:12 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:03:08

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered 'Oral (ORAL)' | Janna Martinez (b) (4) | 07 Aug 2020 22:57:12 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:03:08

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered empty. | Janna Martinez (b) (4) | 07 Aug 2020 22:57:12 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:03:08

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | (b) (4), (b) (6) | 11 Aug 2020 08:38:00 |
| User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | | |
| Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' | Janna Martinez (b) (4) | 07 Aug 2020 22:57:19 |
| answered with 'DATA CORRECT AS ENTERED' (Site from System). | (b) (4) | |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | System | 07 Aug 2020 22:57:12 |
| User entered 'UN Jan 2010' | Janna Martinez (b) (4) | 07 Aug 2020 22:57:12 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:03:08

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered '0' | Janna Martinez (b) (4) | 07 Aug 2020 22:57:12 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:03:08

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered 'Yes (Y)' | Janna Martinez (b) (4) | 07 Aug 2020 22:57:12 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:03:08

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered empty. | Janna Martinez (b) (4) | 07 Aug 2020 22:57:12 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:03:08

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered 'No (N)' | Janna Martinez (b) (4) | 07 Aug 2020 22:57:12 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:03:08

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 07 Aug 2020 22:57:12 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:03:08

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 07 Aug 2020 22:57:12 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:03:08

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '802 (802)' | System | 07 Aug 2020 22:57:12 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:03:08

Name of Medication

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: LOW-CEILING DIURETICS, THIAZIDES, ATC: THIAZIDES, PLAIN, PRODUCT: HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 07 Aug 2020 22:59:25 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 07 Aug 2020 22:59:25 |
| Data point term sent to Coder | System | 07 Aug 2020 22:58:56 |
| User entered 'HYDROCHLOROTHIAZIDE' | Janna Martinez (b) (4) | 07 Aug 2020 22:58:04 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:03:08

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered 'No (N)' | Janna Martinez (b) (4) | 07 Aug 2020 22:58:04 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:03:08

[Indication](#)

| Audit | User | Time (GMT) |
|-----------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered 'HYPERTENSION' | Janna Martinez (b) (4) | 07 Aug 2020 22:58:04 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:03:08

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered '12' | Janna Martinez (b) (4) | 07 Aug 2020 22:58:04 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:03:08

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered 'mg (mg)' | Janna Martinez (b) (4) | 07 Aug 2020 22:58:04 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:03:08

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered empty. | Janna Martinez (b) (4) | 07 Aug 2020 22:58:04 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:03:08

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered 'once daily (QD)' | Janna Martinez (b) (4) | 07 Aug 2020 22:58:04 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:03:08

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered empty. | Janna Martinez (b) (4) | 07 Aug 2020 22:58:04 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:03:08

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered 'Oral (ORAL)' | Janna Martinez (b) (4) | 07 Aug 2020 22:58:04 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:03:08

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered empty. | Janna Martinez (b) (4) | 07 Aug 2020 22:58:04 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:03:08

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | (b) (4), (b) (6) | 11 Aug 2020 08:38:09 |
| User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | | |
| Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' | Janna Martinez (b) (4) | 07 Aug 2020 22:58:13 |
| answered with 'DATA CORRECT AS ENTERED' (Site from System). | (b) (4) | |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | System | 07 Aug 2020 22:58:04 |
| User entered 'UN Jan 2003' | Janna Martinez (b) (4) | 07 Aug 2020 22:58:04 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:03:08

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered '0' | Janna Martinez (b) (4) | 07 Aug 2020 22:58:04 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:03:08

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered 'Yes (Y)' | Janna Martinez (b) (4) | 07 Aug 2020 22:58:04 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:03:08

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered empty. | Janna Martinez (b) (4) | 07 Aug 2020 22:58:04 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:03:08

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered 'No (N)' | Janna Martinez (b) (4) | 07 Aug 2020 22:58:04 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:03:08

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 07 Aug 2020 22:58:04 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:03:08

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 07 Aug 2020 22:58:04 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:03:08

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 07 Aug 2020 22:58:04 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:03:08

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: POTASSIUM, ATC: POTASSIUM, PRODUCT: POTASSIUM - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 07 Aug 2020 23:01:26 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 07 Aug 2020 23:01:26 |
| | (b) (4) | |
| Data point term sent to Coder | System | 07 Aug 2020 23:00:59 |
| User entered 'POTASSIUM' | Janna Martinez (b) (4) | 07 Aug 2020 23:00:07 |
| | | |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:03:08

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| User closed query 'Per CDM: It appears this medication was used for prophylaxis; however, Prophylaxis = No. Please review, reconcile and update accordingly.' (Site from DM). | (b) (4), (b) (6) | 15 Sep 2020 07:48:01 |
| Query 'Per CDM: It appears this medication was used for prophylaxis; however, Prophylaxis = No. Please review, reconcile and update accordingly.' answered with 'updated' (Site from DM). | marissa Mueller (b) (4) | 14 Sep 2020 18:49:33 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | marissa Mueller (b) (4) | 14 Sep 2020 18:49:27 |
| User opened query 'Per CDM: It appears this medication was used for prophylaxis; however, Prophylaxis = No. Please review, reconcile and update accordingly.' (Site from DM). | (b) (4), (b) (6) | 14 Sep 2020 12:15:20 |
| User entered 'No (N)' | Janna Martinez (b) (4) | 07 Aug 2020 23:00:07 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:03:08

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered 'NUTRITIONAL SUPPLEMENT' | Janna Martinez (b) (4) | 07 Aug 2020 23:00:07 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:03:08

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| User entered '10' | Janna Martinez (b) (4) (b) (4) | 07 Aug 2020 23:00:07 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:03:08

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered 'mg (mg)' | Janna Martinez (b) (4) | 07 Aug 2020 23:00:07 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:03:08

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered empty. | Janna Martinez (b) (4) | 07 Aug 2020 23:00:07 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:03:08

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered 'once daily (QD)' | Janna Martinez (b) (4) | 07 Aug 2020 23:00:07 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:03:08

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered empty. | Janna Martinez (b) (4) | 07 Aug 2020 23:00:07 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:03:08

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered 'Oral (ORAL)' | Janna Martinez (b) (4) | 07 Aug 2020 23:00:07 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:03:08

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered empty. | Janna Martinez (b) (4) | 07 Aug 2020 23:00:07 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:03:08

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | (b) (4), (b) (6) | 11 Aug 2020 08:38:17 |
| User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | | |
| Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' | Janna Martinez (b) (4) | 07 Aug 2020 23:00:13 |
| answered with 'DATA CORRECT AS ENTERED' (Site from System). | (b) (4) | |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | System | 07 Aug 2020 23:00:07 |
| User entered 'UN Jun 2014' | Janna Martinez (b) (4) | 07 Aug 2020 23:00:07 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:03:08

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered '0' | Janna Martinez (b) (4) | 07 Aug 2020 23:00:07 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:03:08

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered 'Yes (Y)' | Janna Martinez (b) (4) | 07 Aug 2020 23:00:07 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:03:08

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered empty. | Janna Martinez (b) (4) | 07 Aug 2020 23:00:07 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:03:08

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered 'No (N)' | Janna Martinez (b) (4) | 07 Aug 2020 23:00:07 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:03:08

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 07 Aug 2020 23:00:07 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:03:08

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 07 Aug 2020 23:00:07 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:03:08

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 07 Aug 2020 23:00:07 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:03:08

Name of Medication

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: H2-RECEPTOR ANTAGONISTS, PRODUCT: RANITIDINE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 14 Aug 2020 04:47:18 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 14 Aug 2020 04:47:18 |
| | (b) (4) | |
| Data point term sent to Coder | System | 07 Aug 2020 23:04:03 |
| User entered 'RANITIDINE' | Janna Martinez (b) (4) | 07 Aug 2020 23:03:14 |
| | | |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:03:08

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered 'No (N)' | Janna Martinez (b) (4) | 07 Aug 2020 23:03:14 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:03:08

[Indication](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered 'GASTROESOPHAGEAL REFLUX DISORDER' | Janna Martinez (b) (4) | 07 Aug 2020 23:03:14 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:03:08

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered '150' | Janna Martinez (b) (4) | 07 Aug 2020 23:03:14 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:03:08

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered 'mg (mg)' | Janna Martinez (b) (4) | 07 Aug 2020 23:03:14 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:03:08

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered empty. | Janna Martinez (b) (4) | 07 Aug 2020 23:03:14 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:03:08

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered 'once daily (QD)' | Janna Martinez (b) (4) | 07 Aug 2020 23:03:14 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:03:08

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered empty. | Janna Martinez (b) (4) | 07 Aug 2020 23:03:14 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:03:08

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered 'Oral (ORAL)' | Janna Martinez (b) (4) | 07 Aug 2020 23:03:14 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:03:08

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered empty. | Janna Martinez (b) (4) | 07 Aug 2020 23:03:14 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:03:08

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | (b) (4), (b) (6) | 11 Aug 2020 08:38:29 |
| User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | | |
| Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' | Janna Martinez (b) (4) | 07 Aug 2020 23:03:51 |
| answered with 'DATA CORRECT AS ENTERED' (Site from System). | (b) (4) | |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | System | 07 Aug 2020 23:03:14 |
| User entered 'UN Jan 2010' | Janna Martinez (b) (4) | 07 Aug 2020 23:03:14 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:03:08

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered '0' | Janna Martinez (b) (4) | 07 Aug 2020 23:03:14 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:03:08

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered 'Yes (Y)' | Janna Martinez (b) (4) | 07 Aug 2020 23:03:14 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:03:08

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered empty. | Janna Martinez (b) (4) | 07 Aug 2020 23:03:14 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:03:08

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered 'No (N)' | Janna Martinez (b) (4) | 07 Aug 2020 23:03:14 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:03:08

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 07 Aug 2020 23:03:14 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:03:08

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 07 Aug 2020 23:03:14 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:03:08

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 07 Aug 2020 23:03:14 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:03:08

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 07 Aug 2020 23:08:13 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 07 Aug 2020 23:08:13 |
| | (b) (4) | |
| Data point term sent to Coder | System | 07 Aug 2020 23:07:05 |
| User entered 'ASPIRIN' | Janna Martinez (b) (4) | 07 Aug 2020 23:06:30 |
| | | |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:03:08

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered 'Yes (Y)' | Janna Martinez (b) (4) | 07 Aug 2020 23:06:30 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:03:08

[Indication](#)

| Audit | User | Time (GMT) |
|------------------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered 'CARDIAC PROPHYLAXIS' | Janna Martinez (b) (4) | 07 Aug 2020 23:06:30 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:03:08

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered '81' | Janna Martinez (b) (4) | 07 Aug 2020 23:06:30 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:03:08

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered 'mg (mg)' | Janna Martinez (b) (4) | 07 Aug 2020 23:06:30 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:03:08

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered empty. | Janna Martinez (b) (4) | 07 Aug 2020 23:06:30 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:03:08

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered 'once daily (QD)' | Janna Martinez (b) (4) | 07 Aug 2020 23:06:30 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:03:08

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered empty. | Janna Martinez (b) (4) | 07 Aug 2020 23:06:30 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:03:08

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered 'Oral (ORAL)' | Janna Martinez (b) (4) | 07 Aug 2020 23:06:30 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:03:08

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered empty. | Janna Martinez (b) (4) | 07 Aug 2020 23:06:30 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:03:08

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | (b) (4), (b) (6) | 11 Aug 2020 08:38:37 |
| User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | | |
| Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' | Janna Martinez (b) (4) | 07 Aug 2020 23:06:35 |
| answered with 'DATA CORRECT AS ENTERED' (Site from System). | (b) (4) | |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | System | 07 Aug 2020 23:06:30 |
| User entered 'UN Jan 1988' | Janna Martinez (b) (4) | 07 Aug 2020 23:06:30 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:03:08

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered '0' | Janna Martinez (b) (4) | 07 Aug 2020 23:06:30 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:03:08

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered 'Yes (Y)' | Janna Martinez (b) (4) | 07 Aug 2020 23:06:30 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:03:08

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered empty. | Janna Martinez (b) (4) | 07 Aug 2020 23:06:30 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:03:08

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered 'No (N)' | Janna Martinez (b) (4) | 07 Aug 2020 23:06:30 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:03:08

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 07 Aug 2020 23:06:30 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:03:08

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 07 Aug 2020 23:06:30 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:03:08

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 07 Aug 2020 23:06:30 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:03:08

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, COMBINATIONS WITH VITAMIN D AND/OR OTHER DRUGS, PRODUCT: CALCIUM;VITAMIN D NOS - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 12 Aug 2020 13:13:31 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 12 Aug 2020 13:13:31 |
| | (b) (4) | |
| Data point term sent to Coder | System | 07 Aug 2020 23:08:07 |
| User entered 'CALCIUM 1200 MG /VITAMIN D 1000 IU' | Janna Martinez (b) (4) | 07 Aug 2020 23:07:47 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:03:08

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| User closed query 'Per CDM: It appears this medication was used for prophylaxis; however, Prophylaxis = No. Please review, reconcile and update accordingly.' (Site from DM). | (b) (4), (b) (6) | 15 Sep 2020 07:48:21 |
| Query 'Per CDM: It appears this medication was used for prophylaxis; however, Prophylaxis = No. Please review, reconcile and update accordingly.' answered with 'updated' (Site from DM). | marissa Mueller (b) (4) | 14 Sep 2020 18:49:46 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | marissa Mueller (b) (4) | 14 Sep 2020 18:49:42 |
| User opened query 'Per CDM: It appears this medication was used for prophylaxis; however, Prophylaxis = No. Please review, reconcile and update accordingly.' (Site from DM). | (b) (4), (b) (6) | 14 Sep 2020 12:15:35 |
| User entered 'No (N)' | Janna Martinez (b) (4) | 07 Aug 2020 23:07:47 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:03:08

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered 'NUTRITIONAL SUPPLEMENT' | Janna Martinez (b) (4) | 07 Aug 2020 23:07:47 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:03:08

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered '2' | Janna Martinez (b) (4) | 07 Aug 2020 23:07:47 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:03:08

[Dose unit](#)

| Audit | User | Time (GMT) |
|--------------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered 'tablet (TABLET)' | Janna Martinez (b) (4) | 07 Aug 2020 23:07:47 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:03:08

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered empty. | Janna Martinez (b) (4) | 07 Aug 2020 23:07:47 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:03:08

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered 'once daily (QD)' | Janna Martinez (b) (4) | 07 Aug 2020 23:07:47 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:03:08

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered empty. | Janna Martinez (b) (4) | 07 Aug 2020 23:07:47 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:03:08

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered 'Oral (ORAL)' | Janna Martinez (b) (4) | 07 Aug 2020 23:07:47 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:03:08

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered empty. | Janna Martinez (b) (4) | 07 Aug 2020 23:07:47 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:03:08

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | (b) (4), (b) (6) | 11 Aug 2020 08:38:44 |
| User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | | |
| Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' | Janna Martinez (b) (4) | 07 Aug 2020 23:07:52 |
| answered with 'DATA CORRECT AS ENTERED' (Site from System). | (b) (4) | |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | System | 07 Aug 2020 23:07:47 |
| User entered 'UN Jan 1988' | Janna Martinez (b) (4) | 07 Aug 2020 23:07:47 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:03:08

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered '0' | Janna Martinez (b) (4) | 07 Aug 2020 23:07:47 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:03:08

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered 'Yes (Y)' | Janna Martinez (b) (4) | 07 Aug 2020 23:07:47 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:03:08

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered empty. | Janna Martinez (b) (4) | 07 Aug 2020 23:07:47 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:03:08

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered 'No (N)' | Janna Martinez (b) (4) | 07 Aug 2020 23:07:47 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:03:08

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 07 Aug 2020 23:07:47 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:03:08

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 07 Aug 2020 23:07:47 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:03:08

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 07 Aug 2020 23:07:47 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:03:08

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: MAGNESIUM, PRODUCT: MAGNESIUM - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 07 Aug 2020 23:10:15 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 07 Aug 2020 23:10:15 |
| Data point term sent to Coder | System | 07 Aug 2020 23:09:08 |
| User entered 'MAGNESIUM' | Janna Martinez (b) (4) | 07 Aug 2020 23:08:32 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:03:08

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| User closed query 'Per CDM: It appears this medication was used for prophylaxis; however, Prophylaxis = No. Please review, reconcile and update accordingly.' (Site from DM). | (b) (4), (b) (6) | 15 Sep 2020 07:48:52 |
| Query 'Per CDM: It appears this medication was used for prophylaxis; however, Prophylaxis = No. Please review, reconcile and update accordingly.' answered with 'updated' (Site from DM). | marissa Mueller (b) (4) | 14 Sep 2020 18:49:53 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | marissa Mueller (b) (4) | 14 Sep 2020 18:49:50 |
| User opened query 'Per CDM: It appears this medication was used for prophylaxis; however, Prophylaxis = No. Please review, reconcile and update accordingly.' (Site from DM). | (b) (4), (b) (6) | 14 Sep 2020 12:15:46 |
| User entered 'No (N)' | Janna Martinez (b) (4) | 07 Aug 2020 23:08:32 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:03:08

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered 'NUTRITIONAL SUPPLEMENT' | Janna Martinez (b) (4) | 07 Aug 2020 23:08:32 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:03:08

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered '400' | Janna Martinez (b) (4) | 07 Aug 2020 23:08:32 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:03:08

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered 'mg (mg)' | Janna Martinez (b) (4) | 07 Aug 2020 23:08:32 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:03:08

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered empty. | Janna Martinez (b) (4) | 07 Aug 2020 23:08:32 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:03:08

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered 'once daily (QD)' | Janna Martinez (b) (4) | 07 Aug 2020 23:08:32 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:03:08

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered empty. | Janna Martinez (b) (4) | 07 Aug 2020 23:08:32 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:03:08

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered 'Oral (ORAL)' | Janna Martinez (b) (4) | 07 Aug 2020 23:08:32 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:03:08

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered empty. | Janna Martinez (b) (4) | 07 Aug 2020 23:08:32 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:03:08

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | (b) (4), (b) (6) | 11 Aug 2020 08:38:54 |
| User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | | |
| Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' | Janna Martinez (b) (4) | 07 Aug 2020 23:08:41 |
| answered with 'DATA CORRECT AS ENTERED' (Site from System). | (b) (4) | |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | System | 07 Aug 2020 23:08:32 |
| User entered 'UN Jan 1988' | Janna Martinez (b) (4) | 07 Aug 2020 23:08:32 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:03:08

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered '0' | Janna Martinez (b) (4) | 07 Aug 2020 23:08:32 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:03:08

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered 'Yes (Y)' | Janna Martinez (b) (4) | 07 Aug 2020 23:08:32 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:03:08

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered empty. | Janna Martinez (b) (4) | 07 Aug 2020 23:08:32 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:03:08

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered 'No (N)' | Janna Martinez (b) (4) | 07 Aug 2020 23:08:32 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:03:08

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 07 Aug 2020 23:08:32 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:03:08

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 07 Aug 2020 23:08:32 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:03:08

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 07 Aug 2020 23:08:32 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:03:08

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User coded data point as ATC: VARIOUS, ATC: GENERAL NUTRIENTS, ATC: OTHER NUTRIENTS, ATC: AMINO ACIDS, INCL. COMBINATIONS WITH POLYPEPTIDES, PRODUCT: LYSINE, PRODUCTSYNONYM: L-LYSINE [LYSINE] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 15 Aug 2020 00:08:46 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 15 Aug 2020 00:08:46 |
| | (b) (4) | |
| Data point term sent to Coder | System | 07 Aug 2020 23:10:12 |
| User entered 'L-LYSINE' | Janna Martinez (b) (4) | 07 Aug 2020 23:09:24 |
| | | |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:03:08

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| User closed query 'Per CDM: It appears this medication was used for prophylaxis; however, Prophylaxis = No. Please review, reconcile and update accordingly.' (Site from DM). | (b) (4), (b) (6) | 15 Sep 2020 07:48:57 |
| Query 'Per CDM: It appears this medication was used for prophylaxis; however, Prophylaxis = No. Please review, reconcile and update accordingly.' answered with 'updated' (Site from DM). | marissa Mueller (b) (4) | 14 Sep 2020 18:50:03 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | marissa Mueller (b) (4) | 14 Sep 2020 18:49:57 |
| User opened query 'Per CDM: It appears this medication was used for prophylaxis; however, Prophylaxis = No. Please review, reconcile and update accordingly.' (Site from DM). | (b) (4), (b) (6) | 14 Sep 2020 12:15:56 |
| User entered 'No (N)' | Janna Martinez (b) (4) | 07 Aug 2020 23:09:24 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:03:08

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered 'NUTRITIONAL SUPPLEMENT' | Janna Martinez (b) (4) | 07 Aug 2020 23:09:24 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:03:08

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| User entered '500' | Janna Martinez (b) (4) (b) (4) | 07 Aug 2020 23:09:24 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:03:08

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered 'mg (mg)' | Janna Martinez (b) (4) | 07 Aug 2020 23:09:24 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:03:08

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered empty. | Janna Martinez (b) (4) | 07 Aug 2020 23:09:24 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:03:08

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered 'once daily (QD)' | Janna Martinez (b) (4) | 07 Aug 2020 23:09:24 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:03:08

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered empty. | Janna Martinez (b) (4) | 07 Aug 2020 23:09:24 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:03:08

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered 'Oral (ORAL)' | Janna Martinez (b) (4) | 07 Aug 2020 23:09:24 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:03:08

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered empty. | Janna Martinez (b) (4) | 07 Aug 2020 23:09:24 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:03:08

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | (b) (4), (b) (6) | 11 Aug 2020 08:39:07 |
| User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | | |
| Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' | Janna Martinez (b) (4) | 07 Aug 2020 23:09:29 |
| answered with 'DATA CORRECT AS ENTERED' (Site from System). | (b) (4) | |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | System | 07 Aug 2020 23:09:24 |
| User entered 'UN Jan 1988' | Janna Martinez (b) (4) | 07 Aug 2020 23:09:24 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:03:08

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered '0' | Janna Martinez (b) (4) | 07 Aug 2020 23:09:24 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:03:08

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered 'Yes (Y)' | Janna Martinez (b) (4) | 07 Aug 2020 23:09:24 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:03:08

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered empty. | Janna Martinez (b) (4) | 07 Aug 2020 23:09:24 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:03:08

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered 'No (N)' | Janna Martinez (b) (4) | 07 Aug 2020 23:09:24 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:03:08

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 07 Aug 2020 23:09:24 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:03:08

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 07 Aug 2020 23:09:24 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:03:08

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 07 Aug 2020 23:09:24 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:03:08

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: OTHER OPHTHALMOLOGICALS, ATC: OTHER OPHTHALMOLOGICALS, PRODUCT: XANTOFYL, PRODUCTSYNONYM: LUTEIN [XANTOFYL] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 11 Aug 2020 13:21:21 |
| User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 11 Aug 2020 13:21:21 |
| Data point term sent to Coder | System | 07 Aug 2020 23:11:13 |
| User entered 'LUTEIN' | Janna Martinez (b) (4) | 07 Aug 2020 23:10:15 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:03:08

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| User closed query 'Per CDM: It appears this medication was used for prophylaxis; however, Prophylaxis = No. Please review, reconcile and update accordingly.' (Site from DM). | (b) (4), (b) (6) | 15 Sep 2020 07:49:00 |
| Query 'Per CDM: It appears this medication was used for prophylaxis; however, Prophylaxis = No. Please review, reconcile and update accordingly.' answered with 'updaetd' (Site from DM). | marissa Mueller (b) (4) | 14 Sep 2020 18:50:12 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | marissa Mueller (b) (4) | 14 Sep 2020 18:50:09 |
| User opened query 'Per CDM: It appears this medication was used for prophylaxis; however, Prophylaxis = No. Please review, reconcile and update accordingly.' (Site from DM). | (b) (4), (b) (6) | 14 Sep 2020 12:16:08 |
| User entered 'No (N)' | Janna Martinez (b) (4) | 07 Aug 2020 23:10:15 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:03:08

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered 'NUTRITIONAL SUPPLEMENT' | Janna Martinez (b) (4) | 07 Aug 2020 23:10:15 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:03:08

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered '20' | Janna Martinez (b) (4) | 07 Aug 2020 23:10:15 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:03:08

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered 'mg (mg)' | Janna Martinez (b) (4) | 07 Aug 2020 23:10:15 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:03:08

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered empty. | Janna Martinez (b) (4) | 07 Aug 2020 23:10:15 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:03:08

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered 'once daily (QD)' | Janna Martinez (b) (4) | 07 Aug 2020 23:10:15 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:03:08

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered empty. | Janna Martinez (b) (4) | 07 Aug 2020 23:10:15 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:03:08

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered 'Oral (ORAL)' | Janna Martinez (b) (4) | 07 Aug 2020 23:10:15 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:03:08

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered empty. | Janna Martinez (b) (4) | 07 Aug 2020 23:10:15 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:03:08

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | (b) (4), (b) (6) | 11 Aug 2020 08:39:17 |
| User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | | |
| Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' | Janna Martinez (b) (4) | 07 Aug 2020 23:10:22 |
| answered with 'DATA CORRECT AS ENTERED' (Site from System). | (b) (4) | |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | System | 07 Aug 2020 23:10:15 |
| User entered 'UN Jan 1988' | Janna Martinez (b) (4) | 07 Aug 2020 23:10:15 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:03:08

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered '0' | Janna Martinez (b) (4) | 07 Aug 2020 23:10:15 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:03:08

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered 'Yes (Y)' | Janna Martinez (b) (4) | 07 Aug 2020 23:10:15 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:03:08

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered empty. | Janna Martinez (b) (4) | 07 Aug 2020 23:10:15 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:03:08

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered 'No (N)' | Janna Martinez (b) (4) | 07 Aug 2020 23:10:15 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:03:08

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 07 Aug 2020 23:10:15 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:03:08

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 07 Aug 2020 23:10:15 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:03:08

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 07 Aug 2020 23:10:15 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:03:08

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User coded data point as ATC: VARIOUS, ATC: GENERAL NUTRIENTS, ATC: OTHER NUTRIENTS, ATC: OTHER COMBINATIONS OF NUTRIENTS, PRODUCT: FISH OIL - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 07 Aug 2020 23:12:15 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 07 Aug 2020 23:12:15 |
| | (b) (4) | |
| Data point term sent to Coder | System | 07 Aug 2020 23:11:15 |
| User entered 'FISH OIL' | Janna Martinez (b) (4) | 07 Aug 2020 23:10:55 |
| | | |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:03:08

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| User closed query 'Per CDM: It appears this medication was used for prophylaxis; however, Prophylaxis = No. Please review, reconcile and update accordingly.' (Site from DM). | (b) (4), (b) (6) | 15 Sep 2020 07:49:05 |
| Query 'Per CDM: It appears this medication was used for prophylaxis; however, Prophylaxis = No. Please review, reconcile and update accordingly.' answered with 'udpated' (Site from DM). | marissa Mueller (b) (4) | 14 Sep 2020 18:50:20 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | marissa Mueller (b) (4) | 14 Sep 2020 18:50:17 |
| User opened query 'Per CDM: It appears this medication was used for prophylaxis; however, Prophylaxis = No. Please review, reconcile and update accordingly.' (Site from DM). | (b) (4), (b) (6) | 14 Sep 2020 12:16:21 |
| User entered 'No (N)' | Janna Martinez (b) (4) | 07 Aug 2020 23:10:55 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:03:08

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered 'NUTRITIONAL SUPPLEMENT' | Janna Martinez (b) (4) | 07 Aug 2020 23:10:55 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:03:08

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered '1400' | Janna Martinez (b) (4) | 07 Aug 2020 23:10:55 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:03:08

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered 'mg (mg)' | Janna Martinez (b) (4) | 07 Aug 2020 23:10:55 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:03:08

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered empty. | Janna Martinez (b) (4) | 07 Aug 2020 23:10:55 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:03:08

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered 'once daily (QD)' | Janna Martinez (b) (4) | 07 Aug 2020 23:10:55 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:03:08

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered empty. | Janna Martinez (b) (4) | 07 Aug 2020 23:10:55 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:03:08

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered 'Oral (ORAL)' | Janna Martinez (b) (4) | 07 Aug 2020 23:10:55 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:03:08

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered empty. | Janna Martinez (b) (4) | 07 Aug 2020 23:10:55 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:03:08

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | (b) (4), (b) (6) | 11 Aug 2020 08:39:27 |
| User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | | |
| Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' | Janna Martinez (b) (4) | 07 Aug 2020 23:11:04 |
| answered with 'DATA CORRECT AS ENTERED' (Site from System). | (b) (4) | |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | System | 07 Aug 2020 23:10:55 |
| User entered 'UN Jan 1988' | Janna Martinez (b) (4) | 07 Aug 2020 23:10:55 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:03:08

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered '0' | Janna Martinez (b) (4) | 07 Aug 2020 23:10:55 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:03:08

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered 'Yes (Y)' | Janna Martinez (b) (4) | 07 Aug 2020 23:10:55 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:03:08

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered empty. | Janna Martinez (b) (4) | 07 Aug 2020 23:10:55 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:03:08

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered 'No (N)' | Janna Martinez (b) (4) | 07 Aug 2020 23:10:55 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:03:08

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 07 Aug 2020 23:10:55 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:03:08

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 07 Aug 2020 23:10:55 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:03:08

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 07 Aug 2020 23:10:55 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:03:08

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: OTHER HYPNOTICS AND SEDATIVES, PRODUCT: DIPHENHYDRAMINE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 07 Aug 2020 23:13:16 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 07 Aug 2020 23:13:16 |
| | (b) (4) | |
| Data point term sent to Coder | System | 07 Aug 2020 23:12:16 |
| User entered 'DIPHENHYDRAMINE' | Janna Martinez (b) (4) | 07 Aug 2020 23:11:54 |
| | | |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:03:08

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered 'No (N)' | Janna Martinez (b) (4) | 07 Aug 2020 23:11:54 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:03:08

[Indication](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| User closed query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF.' (Site from DM). | (b) (4), (b) (6) | 10 Sep 2020 08:24:27 |
| Query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF.' answered with 'updated' (Site from DM). | marissa Mueller (b) (4) | 09 Sep 2020 16:34:32 |
| User opened query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF.' (Site from DM). | (b) (4), (b) (6) | 06 Sep 2020 15:13:34 |
| User entered 'INSOMNIA' | Janna Martinez (b) (4) | 07 Aug 2020 23:11:54 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:03:08

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered '30' | Janna Martinez (b) (4) | 07 Aug 2020 23:11:54 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:03:08

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered 'mg (mg)' | Janna Martinez (b) (4) | 07 Aug 2020 23:11:54 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:03:08

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered empty. | Janna Martinez (b) (4) | 07 Aug 2020 23:11:54 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:03:08

[Frequency](#)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered 'once daily (QD)' reason for change: Data Entry Error | marissa Mueller (b) (4) | 14 Sep 2020 18:50:59 |
| | (b) (4) | |
| User entered 'other (OTHER)' | Janna Martinez (b) (4) | 07 Aug 2020 23:11:54 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:03:08

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| User closed query 'Per CDM: 'Other' has been selected as a frequency of administration and 'Every night' has been entered. Please consider selecting 'once daily' as one of the available options in the frequency drop-down list provided. Please update as appropriate. | (b) (4), (b) (6) | 15 Sep 2020 10:56:30 |
| ' (Site from DM). | | |
| Query 'Per CDM: 'Other' has been selected as a frequency of administration and 'Every night' has been entered. Please consider selecting 'once daily' as one of the available options in the frequency drop-down list provided. Please update as appropriate. | marissa Mueller (b) (4) | 14 Sep 2020 18:51:03 |
| ' answered with 'updated' (Site from DM). | (b) (4) | |
| User entered empty; reason for change Data Entry Error | marissa Mueller (b) (4) | 14 Sep 2020 18:50:59 |
| | (b) (4) | |
| User opened query 'Per CDM: 'Other' has been selected as a frequency of administration and 'Every night' has been entered. Please consider selecting 'once daily' as one of the available options in the frequency drop-down list provided. Please update as appropriate. | (b) (4), (b) (6) | 11 Sep 2020 08:15:24 |
| ' (Site from DM). | | |
| User entered 'EVERY NIGHT' | Janna Martinez (b) (4) | 07 Aug 2020 23:11:54 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:03:08

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered 'Oral (ORAL)' | Janna Martinez (b) (4) | 07 Aug 2020 23:11:54 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:03:08

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered empty. | Janna Martinez (b) (4) | 07 Aug 2020 23:11:54 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:03:08

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | (b) (4), (b) (6) | 11 Aug 2020 08:39:38 |
| User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | | |
| Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' | Janna Martinez (b) (4) | 07 Aug 2020 23:11:58 |
| answered with 'DATA CORRECT AS ENTERED' (Site from System). | (b) (4) | |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | System | 07 Aug 2020 23:11:54 |
| User entered 'UN Jun 2019' | Janna Martinez (b) (4) | 07 Aug 2020 23:11:54 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:03:08

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered '0' | Janna Martinez (b) (4) | 07 Aug 2020 23:11:54 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:03:08

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered 'Yes (Y)' | Janna Martinez (b) (4) | 07 Aug 2020 23:11:54 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:03:08

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered empty. | Janna Martinez (b) (4) | 07 Aug 2020 23:11:54 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:03:08

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered 'No (N)' | Janna Martinez (b) (4) | 07 Aug 2020 23:11:54 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:03:08

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '1' | System | 14 Sep 2020 18:50:59 |
| User entered empty. | System | 07 Aug 2020 23:11:54 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:03:08

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '1' | System | 14 Sep 2020 18:50:59 |
| User entered empty. | System | 07 Aug 2020 23:11:54 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:03:08

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 14 Sep 2020 18:50:59 |
| User entered empty. | System | 07 Aug 2020 23:11:54 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:03:08

Name of Medication

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: LORATADINE, PRODUCTSYNONYM: CLARITIN [LORATADINE] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 07 Aug 2020 23:14:16 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | (b) (4) | 07 Aug 2020 23:14:16 |
| Data point term sent to Coder | System | 07 Aug 2020 23:13:17 |
| User entered 'CLARITIN' | Janna Martinez (b) (4) | 07 Aug 2020 23:12:37 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:03:08

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered 'No (N)' | Janna Martinez (b) (4) | 07 Aug 2020 23:12:37 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:03:08

[Indication](#)

| Audit | User | Time (GMT) |
|-----------------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered 'SEASONAL ALLERGIES' | Janna Martinez (b) (4) | 07 Aug 2020 23:12:37 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:03:08

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered '10' | Janna Martinez (b) (4) | 07 Aug 2020 23:12:37 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:03:08

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered 'mg (mg)' | Janna Martinez (b) (4) | 07 Aug 2020 23:12:37 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:03:08

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered empty. | Janna Martinez (b) (4) | 07 Aug 2020 23:12:37 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:03:08

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered 'as needed (PRN)' | Janna Martinez (b) (4) | 07 Aug 2020 23:12:37 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:03:08

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered empty. | Janna Martinez (b) (4) | 07 Aug 2020 23:12:37 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:03:08

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered 'Oral (ORAL)' | Janna Martinez (b) (4) | 07 Aug 2020 23:12:37 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:03:08

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered empty. | Janna Martinez (b) (4) | 07 Aug 2020 23:12:37 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:03:08

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | (b) (4), (b) (6) | 11 Aug 2020 08:39:50 |
| User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | | |
| Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' | Janna Martinez (b) (4) | 07 Aug 2020 23:12:43 |
| answered with 'DATA CORRECT AS ENTERED' (Site from System). | (b) (4) | |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | System | 07 Aug 2020 23:12:37 |
| User entered 'UN Jan 2005' | Janna Martinez (b) (4) | 07 Aug 2020 23:12:37 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:03:08

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered '0' | Janna Martinez (b) (4) | 07 Aug 2020 23:12:37 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:03:08

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered 'Yes (Y)' | Janna Martinez (b) (4) | 07 Aug 2020 23:12:37 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:03:08

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered empty. | Janna Martinez (b) (4) | 07 Aug 2020 23:12:37 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:03:08

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered 'No (N)' | Janna Martinez (b) (4) | 07 Aug 2020 23:12:37 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:03:08

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 07 Aug 2020 23:12:37 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:03:08

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 07 Aug 2020 23:12:37 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:03:08

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 07 Aug 2020 23:12:37 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:03:08

Name of Medication

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 14 Aug 2020 00:48:17 |
| User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 14 Aug 2020 00:48:17 |
| Data point term sent to Coder | System | 13 Aug 2020 21:32:10 |
| User entered 'ibuprofen' | marissa Mueller (b) (4) | 13 Aug 2020 21:31:30 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:03:08

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered 'No (N)' | marissa Mueller (b) (4) | 13 Aug 2020 21:31:30 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:03:08

[Indication](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| User closed query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF.' (Site from DM). | (b) (4), (b) (6) | 10 Sep 2020 08:25:41 |
| Query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF.' answered with 'updated' (Site from DM). | marissa Mueller (b) (4) | 09 Sep 2020 16:35:19 |
| User opened query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF.' (Site from DM). | (b) (4), (b) (6) | 06 Sep 2020 15:14:13 |
| User entered 'osteoarthritis, generalized' | marissa Mueller (b) (4) | 13 Aug 2020 21:31:30 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:03:08

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| User entered '600' | marissa Mueller (b) (4) | 13 Aug 2020 21:31:30 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:03:08

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered 'mg (mg)' | marissa Mueller (b) (4) | 13 Aug 2020 21:31:30 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:03:08

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered empty. | marissa Mueller (b) (4) | 13 Aug 2020 21:31:30 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:03:08

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|-------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered 'as needed (PRN)' | marissa Mueller (b) (4) | 13 Aug 2020 21:31:30 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:03:08

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered empty. | marissa Mueller (b) (4) | 13 Aug 2020 21:31:30 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:03:08

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered 'Oral (ORAL)' | marissa Mueller (b) (4) | 13 Aug 2020 21:31:30 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:03:08

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered empty. | marissa Mueller (b) (4) | 13 Aug 2020 21:31:30 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:03:08

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | (b) (4), (b) (6) | 15 Aug 2020 22:49:20 |
| User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | | |
| Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' | marissa Mueller (b) (4) | 13 Aug 2020 21:31:40 |
| answered with 'correct per protocol' (Site from System). | (b) (4) | |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | System | 13 Aug 2020 21:31:30 |
| User entered 'un Jan 2015' | marissa Mueller (b) (4) | 13 Aug 2020 21:31:30 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:03:08

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered '0' | marissa Mueller (b) (4) | 13 Aug 2020 21:31:30 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:03:08

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered 'Yes (Y)' | marissa Mueller (b) (4) | 13 Aug 2020 21:31:30 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:03:08

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered empty. | marissa Mueller (b) (4) | 13 Aug 2020 21:31:30 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:03:08

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered 'No (N)' | marissa Mueller (b) (4) | 13 Aug 2020 21:31:30 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:03:08

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 13 Aug 2020 21:31:30 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:03:08

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 13 Aug 2020 21:31:30 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:03:08

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 13 Aug 2020 21:31:30 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:03:08

Name of Medication

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:21:45 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| User closed query 'Per DM CLR: Con Med was added during the study. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition or previous Adverse Event requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM). | (b) (4), (b) (6) | 12 Oct 2020 10:15:22 |
| Query 'Per DM CLR: Con Med was added during the study. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition or previous Adverse Event requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' answered with 'no change from baseline. lowered dose' (Site from DM). | marissa Mueller (b) (4) | 09 Oct 2020 15:13:28 |
| User opened query 'Per DM CLR: Con Med was added during the study. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition or previous Adverse Event requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM). | (b) (4), (b) (6) | 09 Oct 2020 07:29:13 |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: OXICAMS, PRODUCT: MELOXICAM - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 09 Sep 2020 16:36:42 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:03:08

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| User coded data point as Term Coded data point by | Coder Import (b) (4) | 09 Sep 2020 16:36:42 |
| User: Coder System - version | (b) (4) | |
| WHODrug-Global-B3\\202003. | | |
| Data point term sent to Coder | System | 09 Sep 2020 16:35:44 |
| Coding entries removed. | marissa Mueller (b) (4) | 09 Sep 2020 16:35:39 |
| | (b) (4) | |
| User coded data point as ATC: | Coder Import (b) (4) | 13 Aug 2020 21:34:09 |
| MUSCULO-SKELETAL SYSTEM, ATC: | (b) (4) | |
| ANTIINFLAMMATORY AND ANTIRHEUMATIC | | |
| PRODUCTS, ATC: ANTIINFLAMMATORY AND | | |
| ANTIRHEUMATIC PRODUCTS, | | |
| NON-STERIODS, ATC: OXICAMS, PRODUCT: | | |
| MELOXICAM - version | | |
| WHODrug-Global-B3\\202003. | | |
| User coded data point as Term Coded data point by | Coder Import (b) (4) | 13 Aug 2020 21:34:09 |
| User: Coder System - version | (b) (4) | |
| WHODrug-Global-B3\\202003. | | |
| Data point term sent to Coder | System | 13 Aug 2020 21:33:12 |
| User entered 'meloxicam' | marissa Mueller (b) (4) | 13 Aug 2020 21:32:45 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:03:08

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:21:45 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| User entered 'No (N)' | marissa Mueller (b) (4) | 13 Aug 2020 21:32:45 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:03:08

[Indication](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:21:45 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| User closed query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF.' (Site from DM). | (b) (4), (b) (6) | 10 Sep 2020 08:26:03 |
| Query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF.' answered with 'updated' (Site from DM). | marissa Mueller (b) (4) | 09 Sep 2020 16:35:45 |
| User entered 'OSTEOARTHRITIS, generalized' reason for change: Data Entry Error | (b) (4) | |
| User opened query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF.' (Site from DM). | (b) (4), (b) (6) | 06 Sep 2020 15:14:38 |
| User entered 'osteoarthritis' | marissa Mueller (b) (4) | 13 Aug 2020 21:32:45 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:03:08

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:21:45 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| User entered '15' | marissa Mueller (b) (4) | 13 Aug 2020 21:32:45 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:03:08

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:21:45 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| User entered 'mg (mg)' | marissa Mueller (b) (4) | 13 Aug 2020 21:32:45 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:03:08

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:21:45 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| User entered empty. | marissa Mueller (b) (4) | 13 Aug 2020 21:32:45 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:03:08

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:21:45 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| User entered 'once daily (QD)' | marissa Mueller (b) (4) | 13 Aug 2020 21:32:45 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:03:08

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:21:45 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| User entered empty. | marissa Mueller (b) (4) | 13 Aug 2020 21:32:45 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:03:08

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:21:45 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| User entered 'Oral (ORAL)' | marissa Mueller (b) (4) | 13 Aug 2020 21:32:45 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:03:08

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:21:45 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| User entered empty. | marissa Mueller (b) (4) | 13 Aug 2020 21:32:45 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:03:08

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:21:45 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| User entered '12 Aug 2020' | marissa Mueller (b) (4) | 13 Aug 2020 21:32:45 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:03:08

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:21:45 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| User entered '0' | marissa Mueller (b) (4) | 13 Aug 2020 21:32:45 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:03:08

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:21:45 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| User entered 'No (N)' reason for change: Data Entry Error | Janna Martinez (b) (4) | 30 Sep 2020 16:20:31 |
| | (b) (4) | |
| User entered 'Yes (Y)' | marissa Mueller (b) (4) | 13 Aug 2020 21:32:45 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:03:08

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:21:45 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| User entered '01 Sep 2020' reason for change: Data Entry Error | Janna Martinez (b) (4) | 30 Sep 2020 16:20:31 |
| | (b) (4) | |
| User entered empty. | marissa Mueller (b) (4) | 13 Aug 2020 21:32:45 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:03:08

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:21:45 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| User entered 'No (N)' | marissa Mueller (b) (4) | 13 Aug 2020 21:32:45 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:03:08

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:21:45 |
| User entered '1' | System | 13 Aug 2020 21:32:45 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:03:08

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:21:45 |
| User entered '1' | System | 13 Aug 2020 21:32:45 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:03:08

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:21:45 |
| User entered '804 (804)' | System | 13 Aug 2020 21:32:45 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:03:08

Name of Medication

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OXICAMS, PRODUCT: MELOXICAM - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 01 Oct 2020 23:04:00 |
| User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 01 Oct 2020 23:04:00 |
| Data point term sent to Coder | System | 30 Sep 2020 16:19:13 |
| User entered 'MELOXICAM' | Janna Martinez (b) (4) | 30 Sep 2020 16:19:05 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:03:08

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered 'No (N)' | Janna Martinez (b) (4) | 30 Sep 2020 16:19:05 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:03:08

[Indication](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| User entered 'OSTEOARTHRITIS-GENERALIZED' | Janna Martinez (b) (4) | 30 Sep 2020 16:19:05 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:03:08

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered '7.5' | Janna Martinez (b) (4) | 30 Sep 2020 16:19:05 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:03:08

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered 'mg (mg)' | Janna Martinez (b) (4) | 30 Sep 2020 16:19:05 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:03:08

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered empty. | Janna Martinez (b) (4) | 30 Sep 2020 16:19:05 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:03:08

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered 'once daily (QD)' | Janna Martinez (b) (4) | 30 Sep 2020 16:19:05 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:03:08

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered empty. | Janna Martinez (b) (4) | 30 Sep 2020 16:19:05 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:03:08

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered 'Oral (ORAL)' | Janna Martinez (b) (4) | 30 Sep 2020 16:19:05 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:03:08

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered empty. | Janna Martinez (b) (4) | 30 Sep 2020 16:19:05 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:03:08

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered '02 Sep 2020' | Janna Martinez (b) (4) | 30 Sep 2020 16:19:05 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:03:08

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered '0' | Janna Martinez (b) (4) | 30 Sep 2020 16:19:05 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:03:08

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered 'Yes (Y)' | Janna Martinez (b) (4) | 30 Sep 2020 16:19:05 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:03:08

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered empty. | Janna Martinez (b) (4) | 30 Sep 2020 16:19:05 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:03:08

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| | | |
| User entered 'No (N)' | Janna Martinez (b) (4) | 30 Sep 2020 16:19:05 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:03:08

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 30 Sep 2020 16:19:05 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:03:08

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 30 Sep 2020 16:19:05 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:03:08

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 30 Sep 2020 16:19:05 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:03:08

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:17 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 01 Oct 2020 22:46:58 |
| User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003. | (b) (4) | |
| Data point term sent to Coder | System | 30 Sep 2020 16:22:22 |
| User entered 'INFLUENZA VACCINE' | Janna Martinez (b) (4) | 30 Sep 2020 16:22:18 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:03:08

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:17 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| User entered 'Yes (Y)' | Janna Martinez (b) (4) | 30 Sep 2020 16:22:18 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:03:08

[Indication](#)

| Audit | User | Time (GMT) |
|--------------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:17 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| User entered 'INFLUENZA PROPHALYXIS' | Janna Martinez (b) (4) | 30 Sep 2020 16:22:18 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:03:08

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:17 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| User entered '0.5' | Janna Martinez (b) (4) | 30 Sep 2020 16:22:18 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:03:08

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:17 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| User entered 'mL (mL)' | Janna Martinez (b) (4) | 30 Sep 2020 16:22:18 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:03:08

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:17 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| User entered empty. | Janna Martinez (b) (4) | 30 Sep 2020 16:22:18 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:03:08

[Frequency](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:17 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| User entered 'once (ONCE)' | Janna Martinez (b) (4) | 30 Sep 2020 16:22:18 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:03:08

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:17 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| User entered empty. | Janna Martinez (b) (4) | 30 Sep 2020 16:22:18 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:03:08

[Route of administration](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:17 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| User entered 'Intramuscular (INTRAMUSCULAR)' | Janna Martinez (b) (4) | 30 Sep 2020 16:22:18 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:03:08

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:17 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| User entered empty. | Janna Martinez (b) (4) | 30 Sep 2020 16:22:18 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:03:08

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:17 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| User entered '19 Sep 2020' | Janna Martinez (b) (4) | 30 Sep 2020 16:22:18 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:03:08

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:17 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| User entered '0' | Janna Martinez (b) (4) | 30 Sep 2020 16:22:18 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:03:08

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:17 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| User entered 'No (N)' | Janna Martinez (b) (4) | 30 Sep 2020 16:22:18 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:03:08

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:17 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| User entered '19 Sep 2020' | Janna Martinez (b) (4) | 30 Sep 2020 16:22:18 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:03:08

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:17 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 07 Oct 2020 15:04:19 |
| User entered 'No (N)' | Janna Martinez (b) (4) | 30 Sep 2020 16:22:18 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:03:08

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:17 |
| User entered empty. | System | 30 Sep 2020 16:22:18 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:03:08

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:17 |
| User entered empty. | System | 30 Sep 2020 16:22:18 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:03:08

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:17 |
| User entered empty. | System | 30 Sep 2020 16:22:18 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:03:08

Name of Medication

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:22 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 30 Mar 2021 19:56:27 |
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: SULFONAMIDES AND TRIMETHOPRIM, ATC: COMBINATIONS OF SULFONAMIDES AND TRIMETHOPRIM, INCL. DERIVATIVES, PRODUCT: SULFAMETHOXAZOLE;TRIMETHOPRIM, PRODUCTSYNONYM: BACTRIM DS - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 12 Mar 2021 01:36:56 |
| User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 12 Mar 2021 01:36:56 |
| Data point term sent to Coder | System | 11 Mar 2021 19:27:51 |
| DataPoint Un-verified. | marissa Mueller (b) (4) | 11 Mar 2021 19:27:26 |
| Coding entries removed. | marissa Mueller (b) (4) | 11 Mar 2021 19:27:26 |
| User entered 'BACTRIM DS (80/160mg)' reason for change: Data Entry Error | marissa Mueller (b) (4) | 11 Mar 2021 19:27:26 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: SULFONAMIDES AND TRIMETHOPRIM, ATC: COMBINATIONS OF SULFONAMIDES AND TRIMETHOPRIM, INCL. DERIVATIVES, PRODUCT: SULFAMETHOXAZOLE;TRIMETHOPRIM, PRODUCTSYNONYM: BACTRIM DS - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 09 Dec 2020 19:49:36 |
| 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 19:49:36 |

PRODUCTION RELEASE (v12.003
EAB) (1725)

2452 of 2894

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:03:08

[Name of Medication](#)

| Audit | User | Time (GMT) |
|-------------------------------|-------------------|----------------------|
| Data point term sent to Coder | System | 09 Dec 2020 19:48:47 |
| User entered 'Bactrim DS' | Jeri King (b) (4) | 09 Dec 2020 19:47:51 |
| | | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:03:08

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:22 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'No (N)' | Jeri King (b) (4) | 09 Dec 2020 19:47:51 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:03:08

[Indication](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:22 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'Bladder Infection' | Jeri King (b) (4) | 09 Dec 2020 19:47:51 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:03:08

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:22 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 30 Mar 2021 19:56:27 |
| User closed query 'Per DMCLR(RQ): Please note the changes are made in the medication name for dosage .Kindly make the necessary updates in the dosage field. Thanks ' (Site from DM). | (b) (4), (b) (6) | 18 Mar 2021 02:17:23 |
| Query 'Per DMCLR(RQ): Please note the changes aremarissa Mueller made in the medication name for dosage .Kindly make the necessary updates in the dosage field. Thanks ' answered with 'please, clarify as this is how multiple combo drugs are listed in EDC' (Site from DM). | (b) (4) | 16 Mar 2021 15:23:15 |
| User opened query 'Per DMCLR(RQ): Please note the changes are made in the medication name for dosage .Kindly make the necessary updates in the dosage field. Thanks ' (Site from DM). | (b) (4), (b) (6) | 15 Mar 2021 05:46:05 |
| User closed query 'Per DM CLR: Please review the dosage as this is not the expected dosage for this medication. Please review and either correct dosage or provide explanation for alternate dosage of this medication. Please update eCRF as appropriate.' (Site from DM). | (b) (4), (b) (6) | 15 Mar 2021 05:46:05 |
| Query 'Per DM CLR: Please review the dosage as this is not the expected dosage for this medication. Please review and either correct dosage or provide explanation for alternate dosage of this medication. Please update eCRF as appropriate.' answered with 'updated' (Site from DM). | marissa Mueller (b) (4) | 11 Mar 2021 19:27:31 |
| DataPoint Un-verified. | marissa Mueller (b) (4) | 11 Mar 2021 19:27:26 |
| User entered '1' reason for change: Per Query Resolution | marissa Mueller (b) (4) | 11 Mar 2021 19:27:26 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:03:08

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| User opened query 'Per DM CLR: Please review the dosage as this is not the expected dosage for this medication. Please review and either correct dosage or provide explanation for alternate dosage of this medication. Please update eCRF as appropriate.' (Site from DM). | (b) (4), (b) (6) | 07 Mar 2021 11:32:28 |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:22:24 |
| 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. | (b) (4), (b) (6) | 11 Feb 2021 09:37:03 |
| ' (Site from DM). | | |
| 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. | Riley King (b) (4) | 10 Feb 2021 15:57:27 |
| ' answered with 'reconciled ' (Site from DM). | (b) (4) | |
| DataPoint Un-verified. | Riley King (b) (4) | 10 Feb 2021 15:57:17 |
| | (b) (4) | |
| User entered '80/160' reason for change: Per Query Resolution | Riley King (b) (4) | 10 Feb 2021 15:57:17 |
| | (b) (4) | |
| 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. | (b) (4), (b) (6) | 28 Jan 2021 05:35:51 |
| ' (Site from DM). | | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| | | |
| User entered '1' | Jeri King (b) (4) | 09 Dec 2020 19:47:51 |
| | | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:03:08

[Dose unit](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:22 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 30 Mar 2021 19:56:27 |
| DataPoint Un-verified. | marissa Mueller (b) (4) | 11 Mar 2021 19:27:26 |
| | (b) (4) | |
| User entered 'tablet (TABLET)' reason for change: Per Query Resolution | marissa Mueller (b) (4) | 11 Mar 2021 19:27:26 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 17:22:28 |
| DataPoint Un-verified. | Riley King (b) (4) | 10 Feb 2021 15:57:17 |
| | (b) (4) | |
| User entered 'mg (mg)' reason for change: Per Query Resolution | Riley King (b) (4) | 10 Feb 2021 15:57:17 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| | | |
| User entered 'tablet (TABLET)' | Jeri King (b) (4) | 09 Dec 2020 19:47:51 |
| | | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:03:08

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:22 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered empty. | Jeri King (b) (4) | 09 Dec 2020 19:47:51 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:03:08

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:22 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'once daily (QD)' | Jeri King (b) (4) | 09 Dec 2020 19:47:51 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:03:08

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:22 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered empty. | Jeri King (b) (4) | 09 Dec 2020 19:47:51 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:03:08

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:22 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'Oral (ORAL)' | Jeri King (b) (4) | 09 Dec 2020 19:47:51 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:03:08

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:22 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered empty. | Jeri King (b) (4) | 09 Dec 2020 19:47:51 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:03:08

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:22 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered '30 Nov 2020' | Jeri King (b) (4) | 09 Dec 2020 19:47:51 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:03:08

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:22 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered '0' | Jeri King (b) (4) | 09 Dec 2020 19:47:51 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:03:08

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:22 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'No (N)' | Jeri King (b) (4) | 09 Dec 2020 19:47:51 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:03:08

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:22 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered '03 Dec 2020' | Jeri King (b) (4) | 09 Dec 2020 19:47:51 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:03:08

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:22 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'No (N)' | Jeri King (b) (4) | 09 Dec 2020 19:47:51 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:03:08

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:22 |
| User entered '1' | System | 09 Dec 2020 19:47:51 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:03:08

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:22 |
| User entered '1' | System | 09 Dec 2020 19:47:51 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:03:08

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:22 |
| User entered '804 (804)' | System | 09 Dec 2020 19:47:51 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:03:08

Name of Medication

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: NON-SELECTIVE MONOAMINE REUPTAKE INHIBITORS, PRODUCT: AMITRIPTYLINE HYDROCHLORIDE, PRODUCTSYNONYM: AMITRIPTYLENE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 09 Dec 2020 19:49:36 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 09 Dec 2020 19:49:36 |
| Data point term sent to Coder | System | 09 Dec 2020 19:48:47 |
| User entered 'Amitriptylene' | Jeri King (b) (4) | 09 Dec 2020 19:48:25 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:03:08

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| | | |
| User entered 'No (N)' | Jeri King (b) (4) | 09 Dec 2020 19:48:25 |
| | | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:03:08

[Indication](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| 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 INSOMNIA should be recorded, and update con med indication or provide clarification. ' (Site from DM). | (b) (4), (b) (6) | 11 Feb 2021 09:35:44 |
| 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 INSOMNIA should be recorded, and update con med indication or provide clarification. ' answered with 'Insomnia did not worsen ' (Site from DM). | Colton King (b) (4) (b) (4) | 04 Feb 2021 17:31:55 |
| 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 INSOMNIA should be recorded, and update con med indication or provide clarification. ' (Site from DM). | (b) (4), (b) (6) | 28 Jan 2021 05:23:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'Insomnia' | Jeri King (b) (4) | 09 Dec 2020 19:48:25 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:03:08

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| | | |
| User entered '50' | Jeri King (b) (4) | 09 Dec 2020 19:48:25 |
| | | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:03:08

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| | | |
| User entered 'mg (mg)' | Jeri King (b) (4) | 09 Dec 2020 19:48:25 |
| | | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:03:08

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| | | |
| User entered empty. | Jeri King (b) (4) | 09 Dec 2020 19:48:25 |
| | | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:03:08

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| | | |
| User entered 'once daily (QD)' | Jeri King (b) (4) | 09 Dec 2020 19:48:25 |
| | | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:03:08

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| | | |
| User entered empty. | Jeri King (b) (4) | 09 Dec 2020 19:48:25 |
| | | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:03:08

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| | | |
| User entered 'Oral (ORAL)' | Jeri King (b) (4) | 09 Dec 2020 19:48:25 |
| | | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:03:08

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| | | |
| User entered empty. | Jeri King (b) (4) | 09 Dec 2020 19:48:25 |
| | | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:03:08

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| | | |
| User entered '30 Nov 2020' | Jeri King (b) (4) | 09 Dec 2020 19:48:25 |
| | | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:03:08

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered '0' | Jeri King (b) (4) | 09 Dec 2020 19:48:25 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:03:08

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| | | |
| User entered 'Yes (Y)' | Jeri King (b) (4) | 09 Dec 2020 19:48:25 |
| | | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:03:08

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| | | |
| User entered empty. | Jeri King (b) (4) | 09 Dec 2020 19:48:25 |
| | | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:03:08

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| | | |
| User entered 'No (N)' | Jeri King (b) (4) | 09 Dec 2020 19:48:25 |
| | | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:03:08

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 09 Dec 2020 19:48:25 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:03:08

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 09 Dec 2020 19:48:25 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:03:08

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 09 Dec 2020 19:48:25 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:03:08

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:29 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| 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) | 11 Dec 2020 12:00:48 |
| User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 11 Dec 2020 12:00:48 |
| Data point term sent to Coder | System | 09 Dec 2020 19:49:47 |
| User entered 'Tramadol' | Jeri King (b) (4) | 09 Dec 2020 19:49:21 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:03:08

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:29 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'No (N)' | Jeri King (b) (4) | 09 Dec 2020 19:49:21 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:03:08

[Indication](#)

| Audit | User | Time (GMT) |
|-----------------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:29 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'Postoperative Pain' | Jeri King (b) (4) | 09 Dec 2020 19:49:21 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:03:08

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:29 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered '50' | Jeri King (b) (4) | 09 Dec 2020 19:49:21 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:03:08

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:29 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'mg (mg)' | Jeri King (b) (4) | 09 Dec 2020 19:49:21 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:03:08

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:29 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered empty. | Jeri King (b) (4) | 09 Dec 2020 19:49:21 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:03:08

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:29 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'as needed (PRN)' | Jeri King (b) (4) | 09 Dec 2020 19:49:21 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:03:08

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:29 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered empty. | Jeri King (b) (4) | 09 Dec 2020 19:49:21 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:03:08

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:29 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'Oral (ORAL)' | Jeri King (b) (4) | 09 Dec 2020 19:49:21 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:03:08

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:29 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered empty. | Jeri King (b) (4) | 09 Dec 2020 19:49:21 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:03:08

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:29 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered '03 Dec 2020' | Jeri King (b) (4) | 09 Dec 2020 19:49:21 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:03:08

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:29 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered '0' | Jeri King (b) (4) | 09 Dec 2020 19:49:21 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:03:08

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:29 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'No (N)' reason for change: Data Entry Error | Colton King (b) (4) | 21 Jan 2021 22:02:16 |
| User entered 'Yes (Y)' | Jeri King (b) (4) | 09 Dec 2020 19:49:21 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:03:08

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:29 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered '1 Jan 2021' reason for change: Data Entry Error | Colton King (b) (4) | 21 Jan 2021 22:02:16 |
| User entered empty. | Jeri King (b) (4) | 09 Dec 2020 19:49:21 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:03:08

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:29 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'No (N)' | Jeri King (b) (4) | 09 Dec 2020 19:49:21 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:03:08

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:29 |
| User entered empty. | System | 09 Dec 2020 19:49:21 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:03:08

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:29 |
| User entered empty. | System | 09 Dec 2020 19:49:21 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:03:08

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:29 |
| User entered empty. | System | 09 Dec 2020 19:49:21 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:03:08

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| User closed query 'Per DM CLR: Was the dose of this medication increased because the patient experienced a worsening or exacerbation of the medical history condition/ adverse event being treated? If yes, please add the worsening AE and applicable data to the AE eCRF or provide explanation for addition of new medication. ' (Site from DM). | (b) (4), (b) (6) | 11 Feb 2021 09:35:54 |
| Query 'Per DM CLR: Was the dose of this medication increased because the patient experienced a worsening or exacerbation of the medical history condition/ adverse event being treated? If yes, please add the worsening AE and applicable data to the AE eCRF or provide explanation for addition of new medication. | Colton King (b) (4) | 04 Feb 2021 17:32:50 |
| ' answered with 'Hypertension did not worsen ' (Site from DM). | (b) (4) | |
| User opened query 'Per DM CLR: Was the dose of this medication increased because the patient experienced a worsening or exacerbation of the medical history condition/ adverse event being treated? If yes, please add the worsening AE and applicable data to the AE eCRF or provide explanation for addition of new medication. ' (Site from DM). | (b) (4), (b) (6) | 28 Jan 2021 05:24:39 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: LOW-CEILING DIURETICS, THIAZIDES, ATC: THIAZIDES, PLAIN, PRODUCT: HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\202003. | Coder Import (b) (4) | 22 Dec 2020 22:20:49 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\202003. | Coder Import (b) (4) | 22 Dec 2020 22:20:49 |
| | (b) (4) | |
| Data point term sent to Coder | System | 22 Dec 2020 22:03:43 |
| Coding entries removed. | Riley King (b) (4) | 22 Dec 2020 22:02:50 |
| | (b) (4) | |

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EAB) (1725)

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US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:03:08

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: LOW-CEILING DIURETICS, THIAZIDES, ATC: THIAZIDES, PLAIN, PRODUCT: HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 22 Dec 2020 21:42:54 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 22 Dec 2020 21:42:54 |
| Data point term sent to Coder | System | 22 Dec 2020 21:42:16 |
| User entered 'Hydrochlorothiazide' | Riley King (b) (4) (b) (4) | 22 Dec 2020 21:41:39 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:03:08

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| | | |
| User entered 'No (N)' | Riley King (b) (4) | 22 Dec 2020 21:41:39 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:03:08

[Indication](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| | | |
| User entered 'Hypertention' reason for change: Data Entry Error | Riley King (b) (4) | 22 Dec 2020 22:02:50 |
| | (b) (4) | |
| User entered 'HTN' | Riley King (b) (4) | 22 Dec 2020 21:41:39 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:03:08

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| | | |
| User entered '12.5' | Riley King (b) (4) | 22 Dec 2020 21:41:39 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:03:08

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| | | |
| User entered 'mg (mg)' | Riley King (b) (4) | 22 Dec 2020 21:41:39 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:03:08

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| | | |
| User entered empty. | Riley King (b) (4) | 22 Dec 2020 21:41:39 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:03:08

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| | | |
| User entered 'once daily (QD)' | Riley King (b) (4) | 22 Dec 2020 21:41:39 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:03:08

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| | | |
| User entered empty. | Riley King (b) (4) | 22 Dec 2020 21:41:39 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:03:08

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| | | |
| User entered 'Oral (ORAL)' | Riley King (b) (4) | 22 Dec 2020 21:41:39 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:03:08

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| | | |
| User entered empty. | Riley King (b) (4) | 22 Dec 2020 21:41:39 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:03:08

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| | | |
| User entered '4 Dec 2020' | Riley King (b) (4) | 22 Dec 2020 21:41:39 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:03:08

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| | | |
| User entered '0' | Riley King (b) (4) | 22 Dec 2020 21:41:39 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:03:08

[Ongoing?](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| | | |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 22 Dec 2020 21:43:07 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 22 Dec 2020 21:43:07 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Riley King (b) (4) | 22 Dec 2020 21:43:07 |
| | (b) (4) | |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 22 Dec 2020 21:41:39 |
| User entered empty. | Riley King (b) (4) | 22 Dec 2020 21:41:39 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:03:08

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| | | |
| User entered empty. | Riley King (b) (4) | 22 Dec 2020 21:41:39 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:03:08

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| | | |
| User entered 'No (N)' | Riley King (b) (4) | 22 Dec 2020 21:41:39 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:03:08

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 22 Dec 2020 21:41:39 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:03:08

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 22 Dec 2020 21:41:39 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:03:08

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 22 Dec 2020 21:41:39 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:03:08

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| | | |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: POTASSIUM, ATC: POTASSIUM, PRODUCT: POTASSIUM CHLORIDE, PRODUCTSYNONYM: K-DUR - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 22 Dec 2020 22:00:54 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 22 Dec 2020 22:00:54 |
| | (b) (4) | |
| Data point term sent to Coder | System | 22 Dec 2020 21:59:37 |
| Data point term sent to Coder | System | 22 Dec 2020 21:43:16 |
| User entered 'K-Dur' | Riley King (b) (4) | 22 Dec 2020 21:42:24 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:03:08

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| | | |
| User entered 'No (N)' | Riley King (b) (4) | 22 Dec 2020 21:42:24 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:03:08

[Indication](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| | | |
| User entered 'Hypertension' reason for change: Data Entry Error | Riley King (b) (4) | 22 Dec 2020 21:59:22 |
| | (b) (4) | |
| User entered 'HTN' | Riley King (b) (4) | 22 Dec 2020 21:42:24 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:03:08

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| | | |
| User entered '10' | Riley King (b) (4) | 22 Dec 2020 21:42:24 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:03:08

[Dose unit](#)

| Audit | User | Time (GMT) |
|------------------------------|-----------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| | | |
| User entered 'Other (OTHER)' | Riley King (b) (4) | 22 Dec 2020 21:42:24 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:03:08

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| | | |
| User entered 'mEq' | Riley King (b) (4) | 22 Dec 2020 21:42:24 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:03:08

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| | | |
| User entered 'once daily (QD)' | Riley King (b) (4) | 22 Dec 2020 21:42:24 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:03:08

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| | | |
| User entered empty. | Riley King (b) (4) | 22 Dec 2020 21:42:24 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:03:08

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| | | |
| User entered 'Oral (ORAL)' | Riley King (b) (4) | 22 Dec 2020 21:42:24 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:03:08

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| | | |
| User entered empty. | Riley King (b) (4) | 22 Dec 2020 21:42:24 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:03:08

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| | | |
| User entered '4 Dec 2020' | Riley King (b) (4) | 22 Dec 2020 21:42:24 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:03:08

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| | | |
| User entered '0' | Riley King (b) (4) | 22 Dec 2020 21:42:24 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:03:08

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| | | |
| User entered 'Yes (Y)' | Riley King (b) (4) | 22 Dec 2020 21:42:24 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:03:08

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| | | |
| User entered empty. | Riley King (b) (4) | 22 Dec 2020 21:42:24 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:03:08

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| | | |
| User entered 'No (N)' | Riley King (b) (4) | 22 Dec 2020 21:42:24 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:03:08

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 22 Dec 2020 21:42:24 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:03:08

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 22 Dec 2020 21:42:24 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:03:08

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 22 Dec 2020 21:42:24 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:03:08

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:36 |
| 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: SODIUM CHLORIDE, PRODUCTSYNONYM: NORMAL SALINE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 18 Apr 2021 17:50:58 |
| User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 18 Apr 2021 17:50:58 |
| User signature succeeded. | Troy Holdeman (b) (4) (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: NORMAL SALINE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 23 Dec 2020 00:26:25 |
| User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 23 Dec 2020 00:26:25 |
| Data point term sent to Coder | System | 22 Dec 2020 21:59:39 |
| Data point term sent to Coder | System | 22 Dec 2020 21:45:17 |
| User entered 'Normal Saline' | Riley King (b) (4) (b) (4) | 22 Dec 2020 21:44:47 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:03:08

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:36 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'No (N)' | Riley King (b) (4) | 22 Dec 2020 21:44:47 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:03:08

[Indication](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:36 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'Worsening osteoarthritis right knee' | Riley King (b) (4) | 22 Dec 2020 21:59:34 |
| reason for change: Data Entry Error | (b) (4) | |
| User entered 'worsening OA R knee' | Riley King (b) (4) | 22 Dec 2020 21:44:47 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:03:08

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:36 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered '80' | Riley King (b) (4) | 22 Dec 2020 21:44:47 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:03:08

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:36 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'mL (mL)' | Riley King (b) (4) | 22 Dec 2020 21:44:47 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:03:08

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:36 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered empty. | Riley King (b) (4) | 22 Dec 2020 21:44:47 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:03:08

[Frequency](#)

| Audit | User | Time (GMT) |
|------------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:36 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'other (OTHER)' | Riley King (b) (4) | 22 Dec 2020 21:44:47 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:03:08

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:36 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'every hour' | Riley King (b) (4) | 22 Dec 2020 21:44:47 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:03:08

[Route of administration](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:36 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'Intravenous (INTRAVENOUS)' | Riley King (b) (4) | 22 Dec 2020 21:44:47 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:03:08

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:36 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered empty. | Riley King (b) (4) | 22 Dec 2020 21:44:47 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:03:08

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:36 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered '3 Dec 2020' | Riley King (b) (4) | 22 Dec 2020 21:44:47 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:03:08

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:36 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered '0' | Riley King (b) (4) | 22 Dec 2020 21:44:47 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:03:08

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:36 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'No (N)' | Riley King (b) (4) | 22 Dec 2020 21:44:47 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:03:08

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:36 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered '4 Dec 2020' | Riley King (b) (4) | 22 Dec 2020 21:44:47 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:03:08

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:36 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'No (N)' | Riley King (b) (4) | 22 Dec 2020 21:44:47 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:03:08

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:36 |
| User entered empty. | System | 22 Dec 2020 21:44:47 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:03:08

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:36 |
| User entered empty. | System | 22 Dec 2020 21:44:47 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:03:08

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:36 |
| User entered empty. | System | 22 Dec 2020 21:44:47 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:03:08

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:43 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| 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: CEFAZOLIN SODIUM, PRODUCTSYNONYM: KEFZOL - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 22 Dec 2020 22:02:32 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | (b) (4) | |
| Data point term sent to Coder | System | 22 Dec 2020 22:00:40 |
| Coding entries removed. | Riley King (b) (4) | 22 Dec 2020 21:59:46 |
| | (b) (4) | |
| 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: CEFAZOLIN SODIUM, PRODUCTSYNONYM: KEFZOL - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 22 Dec 2020 21:47:34 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | (b) (4) | |
| Data point term sent to Coder | System | 22 Dec 2020 21:46:18 |
| User entered 'Kefzol' | Riley King (b) (4) | 22 Dec 2020 21:45:47 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:03:08

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:43 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'No (N)' | Riley King (b) (4) | 22 Dec 2020 21:45:47 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:03:08

[Indication](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:43 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'Worsening osteoarthritis right knee' | Riley King (b) (4) | 22 Dec 2020 21:59:46 |
| reason for change: Data Entry Error | (b) (4) | |
| User entered 'Worsening OA R knee' | Riley King (b) (4) | 22 Dec 2020 21:45:47 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:03:08

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:43 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered '2' | Riley King (b) (4) | 22 Dec 2020 21:45:47 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:03:08

[Dose unit](#)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:43 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Feb 2021 22:39:57 |
| User closed query 'please verify as grams for coding purpose' (Site from CRA). | (b) (4), (b) (6) | 01 Feb 2021 22:39:51 |
| Query 'please verify as grams for coding purpose' answered with 'please, clarify ' (Site from CRA). | marissa Mueller (b) (4) | 22 Jan 2021 21:01:49 |
| | (b) (4) | |
| DataPoint Un-verified. | (b) (4), (b) (6) | 22 Jan 2021 19:59:24 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User opened query 'please verify as grams for coding purpose' (Site from CRA). | (b) (4), (b) (6) | 22 Jan 2021 19:46:28 |
| User entered 'g (g)' | Riley King (b) (4) | 22 Dec 2020 21:45:47 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:03:08

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:43 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered empty. | Riley King (b) (4) | 22 Dec 2020 21:45:47 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:03:08

[Frequency](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:43 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'once (ONCE)' | Riley King (b) (4) | 22 Dec 2020 21:45:47 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:03:08

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:43 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered empty. | Riley King (b) (4) | 22 Dec 2020 21:45:47 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:03:08

[Route of administration](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:43 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'Intravenous (INTRAVENOUS)' | Riley King (b) (4) | 22 Dec 2020 21:45:47 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:03:08

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:43 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered empty. | Riley King (b) (4) | 22 Dec 2020 21:45:47 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:03:08

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:43 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered '3 Dec 2020' | Riley King (b) (4) | 22 Dec 2020 21:45:47 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:03:08

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:43 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered '0' | Riley King (b) (4) | 22 Dec 2020 21:45:47 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:03:08

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:43 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'No (N)' | Riley King (b) (4) | 22 Dec 2020 21:45:47 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:03:08

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:43 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered '3 Dec 2020' | Riley King (b) (4) | 22 Dec 2020 21:45:47 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:03:08

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:43 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'No (N)' | Riley King (b) (4) | 22 Dec 2020 21:45:47 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:03:08

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:43 |
| User entered empty. | System | 22 Dec 2020 21:45:47 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:03:08

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:43 |
| User entered empty. | System | 22 Dec 2020 21:45:47 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:03:08

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:43 |
| User entered empty. | System | 22 Dec 2020 21:45:47 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:03:08

Name of Medication

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:50 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: GLYCOPEPTIDE ANTIBACTERIALS, PRODUCT: VANCOMYCIN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 23 Dec 2020 18:33:41 |
| User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 23 Dec 2020 18:33:41 |
| Data point term sent to Coder | System | 22 Dec 2020 22:00:40 |
| Data point term sent to Coder | System | 22 Dec 2020 21:47:19 |
| User entered 'Vancomycin' | Riley King (b) (4) | 22 Dec 2020 21:46:45 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:03:08

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:50 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'No (N)' | Riley King (b) (4) | 22 Dec 2020 21:46:45 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:03:08

[Indication](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:50 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'Worsening osteoarthritis right knee' | Riley King (b) (4) | 22 Dec 2020 21:59:55 |
| reason for change: Data Entry Error | (b) (4) | |
| User entered 'Worsening OA R knee' | Riley King (b) (4) | 22 Dec 2020 21:46:45 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:03:08

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:50 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered '1000' | Riley King (b) (4) | 22 Dec 2020 21:46:45 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:03:08

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:50 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'mg (mg)' | Riley King (b) (4) | 22 Dec 2020 21:46:45 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:03:08

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:50 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered empty. | Riley King (b) (4) | 22 Dec 2020 21:46:45 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:03:08

[Frequency](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:50 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'once (ONCE)' | Riley King (b) (4) | 22 Dec 2020 21:46:45 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:03:08

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:50 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered empty. | Riley King (b) (4) | 22 Dec 2020 21:46:45 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:03:08

[Route of administration](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:50 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'Intravenous (INTRAVENOUS)' | Riley King (b) (4) | 22 Dec 2020 21:46:45 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:03:08

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:50 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered empty. | Riley King (b) (4) | 22 Dec 2020 21:46:45 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:03:08

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:50 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered '3 Dec 2020' | Riley King (b) (4) | 22 Dec 2020 21:46:45 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:03:08

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:50 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered '0' | Riley King (b) (4) | 22 Dec 2020 21:46:45 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:03:08

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:50 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'No (N)' | Riley King (b) (4) | 22 Dec 2020 21:46:45 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:03:08

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:50 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered '3 Dec 2020' | Riley King (b) (4) | 22 Dec 2020 21:46:45 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:03:08

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:50 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'No (N)' | Riley King (b) (4) | 22 Dec 2020 21:46:45 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:03:08

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:50 |
| User entered empty. | System | 22 Dec 2020 21:46:45 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:03:08

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:50 |
| User entered empty. | System | 22 Dec 2020 21:46:45 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:03:08

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:22:50 |
| User entered empty. | System | 22 Dec 2020 21:46:45 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:03:08

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:24:29 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 16 Feb 2021 15:07:24 |
| User closed query 'please verify as Lactated Ringers soln for coding purpose' (Site from CRA). | (b) (4), (b) (6) | 16 Feb 2021 15:07:21 |
| 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) | 22 Jan 2021 20:58:05 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003. | (b) (4) | |
| Data point term sent to Coder | System | 22 Jan 2021 20:57:55 |
| Query 'please verify as Lactated Ringers soln for coding purpose' answered with 'updated' (Site from CRA). | marissa Mueller (b) (4) | 22 Jan 2021 20:57:50 |
| Coding entries removed. | (b) (4) | |
| | marissa Mueller (b) (4) | 22 Jan 2021 20:57:47 |
| User entered 'lactated ringers' reason for change: Data Entry Error | (b) (4) | |
| | marissa Mueller (b) (4) | 22 Jan 2021 20:57:47 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 22 Jan 2021 19:59:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User opened query 'please verify as Lactated Ringers soln for coding purpose' (Site from CRA). | (b) (4), (b) (6) | 22 Jan 2021 19:45:25 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:03:08

Name of Medication

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), COMBINATIONS, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), OTHER COMBINATIONS, PRODUCT: LOSARTAN POTASSIUM;RAMIPRIL, PRODUCTSYNONYM: LR - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 22 Dec 2020 22:02:32 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 22 Dec 2020 22:02:32 |
| Data point term sent to Coder | System | 22 Dec 2020 22:00:40 |
| Coding entries removed. | Riley King (b) (4) (b) (4) | 22 Dec 2020 22:00:05 |
| User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), COMBINATIONS, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), OTHER COMBINATIONS, PRODUCT: LOSARTAN POTASSIUM;RAMIPRIL, PRODUCTSYNONYM: LR - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 22 Dec 2020 21:50:31 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 22 Dec 2020 21:50:31 |
| Data point term sent to Coder | System | 22 Dec 2020 21:48:21 |
| User entered 'LR' | Riley King (b) (4) (b) (4) | 22 Dec 2020 21:47:39 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:03:08

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:24:29 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'No (N)' | Riley King (b) (4) | 22 Dec 2020 21:47:39 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:03:08

[Indication](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:24:29 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'Worsening osteoarthritis right knee' | Riley King (b) (4) | 22 Dec 2020 22:00:05 |
| reason for change: Data Entry Error | (b) (4) | |
| User entered 'Worsening OA R knee' | Riley King (b) (4) | 22 Dec 2020 21:47:39 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:03:08

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:24:29 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered '50' | Riley King (b) (4) | 22 Dec 2020 21:47:39 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:03:08

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:24:29 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'mL (mL)' | Riley King (b) (4) | 22 Dec 2020 21:47:39 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:03:08

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:24:29 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered empty. | Riley King (b) (4) | 22 Dec 2020 21:47:39 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:03:08

[Frequency](#)

| Audit | User | Time (GMT) |
|------------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:24:29 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'other (OTHER)' | Riley King (b) (4) | 22 Dec 2020 21:47:39 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:03:08

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:24:29 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'Every Hour' | Riley King (b) (4) | 22 Dec 2020 21:47:39 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:03:08

[Route of administration](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:24:29 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'Intravenous (INTRAVENOUS)' | Riley King (b) (4) | 22 Dec 2020 21:47:39 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:03:08

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:24:29 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered empty. | Riley King (b) (4) | 22 Dec 2020 21:47:39 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:03:08

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:24:29 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered '3 Dec 2020' | Riley King (b) (4) | 22 Dec 2020 21:47:39 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:03:08

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:24:29 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered '0' | Riley King (b) (4) | 22 Dec 2020 21:47:39 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:03:08

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:24:29 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'No (N)' | Riley King (b) (4) | 22 Dec 2020 21:47:39 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:03:08

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:24:29 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered '3 Dec 2020' | Riley King (b) (4) | 22 Dec 2020 21:47:39 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:03:08

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:24:29 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'No (N)' | Riley King (b) (4) | 22 Dec 2020 21:47:39 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:03:08

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:24:29 |
| User entered empty. | System | 22 Dec 2020 21:47:39 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:03:08

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:24:29 |
| User entered empty. | System | 22 Dec 2020 21:47:39 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:03:08

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:24:29 |
| User entered empty. | System | 22 Dec 2020 21:47:39 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:03:08

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:25:15 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| 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: DEXAMETHASONE, PRODUCTSYNONYM: DECADRON [DEXAMETHASONE] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 22 Dec 2020 21:52:47 |
| User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 22 Dec 2020 21:52:47 |
| Data point term sent to Coder | System | 22 Dec 2020 21:49:23 |
| User entered 'Decadron' | Riley King (b) (4) | 22 Dec 2020 21:48:37 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:03:08

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:25:15 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'No (N)' | Riley King (b) (4) | 22 Dec 2020 21:48:37 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:03:08

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:25:15 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'Nausea-recurrent' | Riley King (b) (4) | 22 Dec 2020 21:48:37 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:03:08

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:25:15 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered '20' | Riley King (b) (4) | 22 Dec 2020 21:48:37 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:03:08

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:25:15 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'mg (mg)' | Riley King (b) (4) | 22 Dec 2020 21:48:37 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:03:08

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:25:15 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered empty. | Riley King (b) (4) | 22 Dec 2020 21:48:37 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:03:08

[Frequency](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:25:15 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'once (ONCE)' | Riley King (b) (4) | 22 Dec 2020 21:48:37 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:03:08

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:25:15 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered empty. | Riley King (b) (4) | 22 Dec 2020 21:48:37 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:03:08

[Route of administration](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:25:15 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'Intravenous (INTRAVENOUS)' | Riley King (b) (4) | 22 Dec 2020 21:48:37 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:03:08

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:25:15 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered empty. | Riley King (b) (4) | 22 Dec 2020 21:48:37 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:03:08

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:25:15 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered '3 Dec 2020' | Riley King (b) (4) | 22 Dec 2020 21:48:37 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:03:08

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:25:15 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered '0' | Riley King (b) (4) | 22 Dec 2020 21:48:37 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:03:08

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:25:15 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'No (N)' | Riley King (b) (4) | 22 Dec 2020 21:48:37 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:03:08

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:25:15 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered '3 Dec 2020' | Riley King (b) (4) | 22 Dec 2020 21:48:37 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:03:08

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:25:15 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'No (N)' | Riley King (b) (4) | 22 Dec 2020 21:48:37 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:03:08

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:25:15 |
| User entered empty. | System | 22 Dec 2020 21:48:37 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:03:08

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:25:15 |
| User entered empty. | System | 22 Dec 2020 21:48:37 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:03:08

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:25:15 |
| User entered empty. | System | 22 Dec 2020 21:48:37 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:03:08

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:25:19 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: PROPULSIVES, ATC: PROPULSIVES, PRODUCT: METOCLOPRAMIDE, PRODUCTSYNONYM: REGLAN [METOCLOPRAMIDE] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 23 Dec 2020 18:25:40 |
| User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 23 Dec 2020 18:25:40 |
| Data point term sent to Coder | System | 22 Dec 2020 21:50:23 |
| User entered 'Reglan' | Riley King (b) (4) | 22 Dec 2020 21:49:33 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:03:08

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:25:19 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'No (N)' | Riley King (b) (4) | 22 Dec 2020 21:49:33 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:03:08

[Indication](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:25:19 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'Nausea- recurrent' | Riley King (b) (4) | 22 Dec 2020 21:49:33 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:03:08

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:25:19 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered '10' | Riley King (b) (4) | 22 Dec 2020 21:49:33 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:03:08

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:25:19 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'mg (mg)' | Riley King (b) (4) | 22 Dec 2020 21:49:33 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:03:08

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:25:19 |
| User signature succeeded. | Troy Holdeman (b) (4) (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered empty. | Riley King (b) (4) (b) (4) | 22 Dec 2020 21:49:33 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:03:08

[Frequency](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:25:19 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'once (ONCE)' | Riley King (b) (4) | 22 Dec 2020 21:49:33 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:03:08

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:25:19 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered empty. | Riley King (b) (4) | 22 Dec 2020 21:49:33 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:03:08

[Route of administration](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:25:19 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'Intravenous (INTRAVENOUS)' | Riley King (b) (4) | 22 Dec 2020 21:49:33 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:03:08

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:25:19 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered empty. | Riley King (b) (4) | 22 Dec 2020 21:49:33 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:03:08

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:25:19 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered '3 Dec 2020' | Riley King (b) (4) | 22 Dec 2020 21:49:33 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:03:08

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:25:19 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered '0' | Riley King (b) (4) | 22 Dec 2020 21:49:33 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:03:08

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:25:19 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'No (N)' | Riley King (b) (4) | 22 Dec 2020 21:49:33 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:03:08

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:25:19 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered '3 Dec 2020' | Riley King (b) (4) | 22 Dec 2020 21:49:33 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:03:08

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:25:19 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'No (N)' | Riley King (b) (4) | 22 Dec 2020 21:49:33 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:03:08

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:25:19 |
| User entered empty. | System | 22 Dec 2020 21:49:33 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:03:08

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:25:19 |
| User entered empty. | System | 22 Dec 2020 21:49:33 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:03:08

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:25:19 |
| User entered empty. | System | 22 Dec 2020 21:49:33 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:03:08

Name of Medication

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:25:23 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 13 Jan 2021 15:19:01 |
| User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 13 Jan 2021 15:19:01 |
| Data point term sent to Coder | System | 22 Dec 2020 21:51:25 |
| User entered 'Zofran' | Riley King (b) (4) | 22 Dec 2020 21:50:35 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:03:08

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:25:23 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'No (N)' | Riley King (b) (4) | 22 Dec 2020 21:50:35 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:03:08

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:25:23 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'Nausea-recurrent' | Riley King (b) (4) | 22 Dec 2020 21:50:35 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:03:08

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:25:23 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered '4' | Riley King (b) (4) | 22 Dec 2020 21:50:35 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:03:08

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:25:23 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'mg (mg)' | Riley King (b) (4) | 22 Dec 2020 21:50:35 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:03:08

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:25:23 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered empty. | Riley King (b) (4) | 22 Dec 2020 21:50:35 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:03:08

[Frequency](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:25:23 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'once (ONCE)' | Riley King (b) (4) | 22 Dec 2020 21:50:35 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:03:08

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:25:23 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered empty. | Riley King (b) (4) | 22 Dec 2020 21:50:35 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:03:08

[Route of administration](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:25:23 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'Intravenous (INTRAVENOUS)' | Riley King (b) (4) | 22 Dec 2020 21:50:35 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:03:08

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:25:23 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered empty. | Riley King (b) (4) | 22 Dec 2020 21:50:35 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:03:08

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:25:23 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered '3 Dec 2020' | Riley King (b) (4) | 22 Dec 2020 21:50:35 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:03:08

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:25:23 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered '0' | Riley King (b) (4) | 22 Dec 2020 21:50:35 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:03:08

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:25:23 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'No (N)' | Riley King (b) (4) | 22 Dec 2020 21:50:35 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:03:08

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:25:23 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered '3 Dec 2020' | Riley King (b) (4) | 22 Dec 2020 21:50:35 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:03:08

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:25:23 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'No (N)' | Riley King (b) (4) | 22 Dec 2020 21:50:35 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:03:08

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:25:23 |
| User entered empty. | System | 22 Dec 2020 21:50:35 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:03:08

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:25:23 |
| User entered empty. | System | 22 Dec 2020 21:50:35 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:03:08

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:25:23 |
| User entered empty. | System | 22 Dec 2020 21:50:35 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:03:08

Name of Medication

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:25:28 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE, PRODUCTSYNONYM: PEPCID [FAMOTIDINE] - version WHODrug-Global-B3\202003. | Coder Import (b) (4) | 25 Dec 2020 18:20:26 |
| User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\202003. | (b) (4) | |
| Data point term sent to Coder | System | 25 Dec 2020 18:04:53 |
| Query 'For coding purposes, the reported trade name can be referenced with different formulations in the standard coding dictionary. Please enter the active ingredient(s) in parenthesis after drug name and please make your changes to the reported term.' canceled (Site from System). | Coder Import (b) (4) | 25 Dec 2020 18:04:29 |
| User opened query 'For coding purposes, the reported trade name can be referenced with different formulations in the standard coding dictionary. Please enter the active ingredient(s) in parenthesis after drug name and please make your changes to the reported term.' (Site from System). | Coder Import (b) (4) | 23 Dec 2020 17:58:40 |
| Data point term sent to Coder | System | 22 Dec 2020 21:51:26 |
| User entered 'Pepcid' | Riley King (b) (4) | 22 Dec 2020 21:51:19 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:03:08

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:25:28 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'No (N)' | Riley King (b) (4) | 22 Dec 2020 21:51:19 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:03:08

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:25:28 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'Nausea-recurrent' | Riley King (b) (4) | 22 Dec 2020 21:51:19 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:03:08

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:25:28 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered '20' | Riley King (b) (4) | 22 Dec 2020 21:51:19 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:03:08

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:25:28 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'mg (mg)' | Riley King (b) (4) | 22 Dec 2020 21:51:19 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:03:08

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:25:28 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered empty. | Riley King (b) (4) | 22 Dec 2020 21:51:19 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:03:08

[Frequency](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:25:28 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'once (ONCE)' | Riley King (b) (4) | 22 Dec 2020 21:51:19 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:03:08

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:25:28 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered empty. | Riley King (b) (4) | 22 Dec 2020 21:51:19 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:03:08

[Route of administration](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:25:28 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'Intravenous (INTRAVENOUS)' | Riley King (b) (4) | 22 Dec 2020 21:51:19 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:03:08

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:25:28 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered empty. | Riley King (b) (4) | 22 Dec 2020 21:51:19 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:03:08

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:25:28 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered '3 Dec 2020' | Riley King (b) (4) | 22 Dec 2020 21:51:19 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:03:08

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:25:28 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered '0' | Riley King (b) (4) | 22 Dec 2020 21:51:19 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:03:08

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:25:28 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'No (N)' | Riley King (b) (4) | 22 Dec 2020 21:51:19 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:03:08

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:25:28 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered '3 Dec 2020' | Riley King (b) (4) | 22 Dec 2020 21:51:19 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:03:08

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:25:28 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'No (N)' | Riley King (b) (4) | 22 Dec 2020 21:51:19 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:03:08

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:25:28 |
| User entered empty. | System | 22 Dec 2020 21:51:19 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:03:08

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:25:28 |
| User entered empty. | System | 22 Dec 2020 21:51:19 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:03:08

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:25:28 |
| User entered empty. | System | 22 Dec 2020 21:51:19 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:03:08

Name of Medication

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:02 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 22 Jan 2021 21:06:12 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 22 Jan 2021 21:06:12 |
| Data point term sent to Coder | System | 22 Jan 2021 21:05:00 |
| Coding entries removed. | marissa Mueller (b) (4) | 22 Jan 2021 21:04:43 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 22 Dec 2020 22:02:32 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 22 Dec 2020 22:02:32 |
| Data point term sent to Coder | System | 22 Dec 2020 22:01:41 |
| Coding entries removed. | Riley King (b) (4) | 22 Dec 2020 22:01:15 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 22 Dec 2020 21:55:34 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 22 Dec 2020 21:55:34 |
| Data point term sent to Coder | System | 22 Dec 2020 21:53:27 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:03:08

[Name of Medication](#)

| Audit | User | Time (GMT) |
|------------------------|-------------------------------|----------------------|
| User entered 'Tylenol' | Riley King (b) (4) (b) (4) | 22 Dec 2020 21:52:47 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:03:08

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:02 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'No (N)' | Riley King (b) (4) | 22 Dec 2020 21:52:47 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:03:08

[Indication](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:02 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Feb 2021 22:41:10 |
| User closed query 'please verify as post op pain as per CM log' (Site from CRA). | (b) (4), (b) (6) | 01 Feb 2021 22:41:04 |
| Query 'please verify as post op pain as per CM log' answered with 'updated' (Site from CRA). | marissa Mueller (b) (4) | 22 Jan 2021 21:04:46 |
| | (b) (4) | |
| User entered 'POST OPERATIVE pain' reason for change: Data Entry Error | marissa Mueller (b) (4) | 22 Jan 2021 21:04:43 |
| | (b) (4) | |
| DataPoint Un-verified. | (b) (4), (b) (6) | 22 Jan 2021 20:00:47 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User opened query 'please verify as post op pain as per CM log' (Site from CRA). | (b) (4), (b) (6) | 22 Jan 2021 19:40:02 |
| User entered 'POST operative constipation' reason for change: Data Entry Error | Riley King (b) (4) | 22 Dec 2020 22:01:15 |
| | (b) (4) | |
| User entered 'Post op pain' | Riley King (b) (4) | 22 Dec 2020 21:52:47 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:03:08

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:02 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered '1000' | Riley King (b) (4) | 22 Dec 2020 21:52:47 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:03:08

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:02 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'mg (mg)' | Riley King (b) (4) | 22 Dec 2020 21:52:47 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:03:08

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:02 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered empty. | Riley King (b) (4) | 22 Dec 2020 21:52:47 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:03:08

[Frequency](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:02 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'three times daily (TID)' | Riley King (b) (4) | 22 Dec 2020 21:52:47 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:03:08

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:02 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered empty. | Riley King (b) (4) | 22 Dec 2020 21:52:47 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:03:08

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:02 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'Oral (ORAL)' | Riley King (b) (4) | 22 Dec 2020 21:52:47 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:03:08

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:02 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered empty. | Riley King (b) (4) | 22 Dec 2020 21:52:47 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:03:08

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:02 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered '3 Dec 2020' | Riley King (b) (4) | 22 Dec 2020 21:52:47 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:03:08

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:02 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered '0' | Riley King (b) (4) | 22 Dec 2020 21:52:47 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:03:08

[Ongoing?](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:02 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Feb 2021 22:41:27 |
| User closed query 'please verify as 1/1/21 as per CM log' (Site from CRA). | (b) (4), (b) (6) | 01 Feb 2021 22:41:22 |
| Query 'please verify as 1/1/21 as per CM log' answered with 'updated' (Site from CRA). | marissa Mueller (b) (4) | 22 Jan 2021 21:05:14 |
| | (b) (4) | |
| User entered 'No (N)' reason for change: Data Entry Error | marissa Mueller (b) (4) | 22 Jan 2021 21:05:11 |
| | (b) (4) | |
| DataPoint Un-verified. | (b) (4), (b) (6) | 22 Jan 2021 20:00:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User opened query 'please verify as 1/1/21 as per CM log' (Site from CRA). | (b) (4), (b) (6) | 22 Jan 2021 19:42:39 |
| User entered 'Yes (Y)' | Riley King (b) (4) | 22 Dec 2020 21:52:47 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:03:08

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:02 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 01 Feb 2021 22:41:30 |
| DataPoint Un-verified. | marissa Mueller (b) (4) | 22 Jan 2021 21:05:11 |
| | (b) (4) | |
| User entered '01 Jan 2021' reason for change: Data Entry Error | marissa Mueller (b) (4) | 22 Jan 2021 21:05:11 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered empty. | Riley King (b) (4) | 22 Dec 2020 21:52:47 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:03:08

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:02 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'No (N)' | Riley King (b) (4) | 22 Dec 2020 21:52:47 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:03:08

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:02 |
| User entered '3' | System | 22 Dec 2020 21:52:47 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:03:08

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:02 |
| User entered '1' | System | 22 Dec 2020 21:52:47 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:03:08

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:02 |
| User entered '804 (804)' | System | 22 Dec 2020 21:52:47 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:03:08

Name of Medication

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:06 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4) | 01 Feb 2021 22:40:43 |
| User closed query 'please verify as Magnesium Oxide for coding purposes' (Site from CRA). | (b) (4), (b) (6) | 01 Feb 2021 22:40:37 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OSMOTICALLY ACTING LAXATIVES, PRODUCT: MAGNESIUM OXIDE - version WHODrug-Global-B3\202003. | Coder Import (b) (4) | 22 Jan 2021 23:45:07 |
| User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\202003. | (b) (4) | 22 Jan 2021 23:45:07 |
| Data point term sent to Coder | System | 22 Jan 2021 21:06:03 |
| Query 'please verify as Magnesium Oxide for coding purposes' answered with 'updated' (Site from CRA). | marissa Mueller (b) (4) | 22 Jan 2021 21:05:34 |
| Coding entries removed. | (b) (4) | 22 Jan 2021 21:05:31 |
| User entered 'magnesium oxide' reason for change: Data Entry Error | marissa Mueller (b) (4) | 22 Jan 2021 21:05:31 |
| DataPoint Un-verified. | (b) (4) | 22 Jan 2021 20:01:02 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User opened query 'please verify as Magnesium Oxide for coding purposes' (Site from CRA). | (b) (4), (b) (6) | 22 Jan 2021 19:40:55 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OSMOTICALLY ACTING LAXATIVES, PRODUCT: MAGNESIUM OXIDE, PRODUCTSYNONYM: MAG-OX - version WHODrug-Global-B3\202003. | Coder Import (b) (4) | 22 Dec 2020 23:43:49 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:03:08

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 22 Dec 2020 23:43:49 |
| Data point term sent to Coder | System | 22 Dec 2020 22:01:41 |
| Data point term sent to Coder | System | 22 Dec 2020 21:54:29 |
| User entered 'Mag ox' | Riley King (b) (4) (b) (4) | 22 Dec 2020 21:53:45 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:03:08

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:06 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'No (N)' | Riley King (b) (4) | 22 Dec 2020 21:53:45 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:03:08

[Indication](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:06 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'POST operative constipation' reason for change: Data Entry Error | Riley King (b) (4) | 22 Dec 2020 22:01:22 |
| User entered 'Post op constipation' | Riley King (b) (4) | 22 Dec 2020 21:53:45 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:03:08

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:06 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered '400' | Riley King (b) (4) | 22 Dec 2020 21:53:45 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:03:08

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:06 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'mg (mg)' | Riley King (b) (4) | 22 Dec 2020 21:53:45 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:03:08

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:06 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered empty. | Riley King (b) (4) | 22 Dec 2020 21:53:45 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:03:08

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:06 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'once daily (QD)' | Riley King (b) (4) | 22 Dec 2020 21:53:45 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:03:08

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:06 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered empty. | Riley King (b) (4) | 22 Dec 2020 21:53:45 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:03:08

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:06 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'Oral (ORAL)' | Riley King (b) (4) | 22 Dec 2020 21:53:45 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:03:08

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:06 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered empty. | Riley King (b) (4) | 22 Dec 2020 21:53:45 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:03:08

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:06 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered '4 Dec 2020' | Riley King (b) (4) | 22 Dec 2020 21:53:45 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:03:08

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:06 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered '0' | Riley King (b) (4) | 22 Dec 2020 21:53:45 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:03:08

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:06 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'No (N)' | Riley King (b) (4) | 22 Dec 2020 21:53:45 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:03:08

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:06 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered '4 Dec 2020' | Riley King (b) (4) | 22 Dec 2020 21:53:45 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:03:08

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:06 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'No (N)' | Riley King (b) (4) | 22 Dec 2020 21:53:45 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:03:08

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:06 |
| User entered '1' | System | 22 Dec 2020 21:53:45 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:03:08

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:06 |
| User entered '1' | System | 22 Dec 2020 21:53:45 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:03:08

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:06 |
| User entered '804 (804)' | System | 22 Dec 2020 21:53:45 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:03:08

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:11 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OSMOTICALLY ACTING LAXATIVES, PRODUCT: MACROGOL 3350, PRODUCTSYNONYM: MIRALAX - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 22 Dec 2020 22:02:48 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 22 Dec 2020 22:02:48 |
| Data point term sent to Coder | System | 22 Dec 2020 22:01:42 |
| Coding entries removed. | Riley King (b) (4) | 22 Dec 2020 22:01:31 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OSMOTICALLY ACTING LAXATIVES, PRODUCT: MACROGOL 3350, PRODUCTSYNONYM: MIRALAX - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 22 Dec 2020 21:55:52 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 22 Dec 2020 21:55:52 |
| Data point term sent to Coder | System | 22 Dec 2020 21:54:29 |
| User entered 'Miralax' | Riley King (b) (4) | 22 Dec 2020 21:54:23 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:03:08

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:11 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'No (N)' | Riley King (b) (4) | 22 Dec 2020 21:54:23 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:03:08

[Indication](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:11 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'POST operative constipation' reason for change: Data Entry Error | Riley King (b) (4) | 22 Dec 2020 22:01:31 |
| User entered 'Post op constipation' | Riley King (b) (4) | 22 Dec 2020 21:54:23 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:03:08

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:11 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered '17' | Riley King (b) (4) | 22 Dec 2020 21:54:23 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:03:08

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:11 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'g (g)' | Riley King (b) (4) | 22 Dec 2020 21:54:23 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:03:08

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:11 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered empty. | Riley King (b) (4) | 22 Dec 2020 21:54:23 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:03:08

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:11 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'once daily (QD)' | Riley King (b) (4) | 22 Dec 2020 21:54:23 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:03:08

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:11 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered empty. | Riley King (b) (4) | 22 Dec 2020 21:54:23 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:03:08

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:11 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'Oral (ORAL)' | Riley King (b) (4) | 22 Dec 2020 21:54:23 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:03:08

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:11 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered empty. | Riley King (b) (4) | 22 Dec 2020 21:54:23 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:03:08

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:11 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered '4 Dec 2020' | Riley King (b) (4) | 22 Dec 2020 21:54:23 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:03:08

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:11 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered '0' | Riley King (b) (4) | 22 Dec 2020 21:54:23 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:03:08

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:11 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'No (N)' | Riley King (b) (4) | 22 Dec 2020 21:54:23 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:03:08

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:11 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered '4 Dec 2020' | Riley King (b) (4) | 22 Dec 2020 21:54:23 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:03:08

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:11 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'No (N)' | Riley King (b) (4) | 22 Dec 2020 21:54:23 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:03:08

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:11 |
| User entered '1' | System | 22 Dec 2020 21:54:23 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:03:08

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:11 |
| User entered '1' | System | 22 Dec 2020 21:54:23 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:03:08

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:11 |
| User entered '804 (804)' | System | 22 Dec 2020 21:54:23 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:03:08

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:17 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: CONTACT LAXATIVES, PRODUCT: SENNOSIDE A+B, PRODUCTSYNONYM: SENNA [SENNOSIDE A+B] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 29 Dec 2020 15:47:18 |
| User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 29 Dec 2020 15:47:18 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: CONTACT LAXATIVES, PRODUCT: INULA HELENIUM ROOT; SENNA ALEXANDRINA LEAF, PRODUCTSYNONYM: SENNA+ - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 23 Dec 2020 18:49:40 |
| User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 23 Dec 2020 18:49:40 |
| Data point term sent to Coder | System | 22 Dec 2020 22:01:42 |
| Data point term sent to Coder | System | 22 Dec 2020 21:55:30 |
| User entered 'Senna' | Riley King (b) (4) | 22 Dec 2020 21:55:00 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:03:08

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:17 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'No (N)' | Riley King (b) (4) | 22 Dec 2020 21:55:00 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:03:08

[Indication](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:17 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'POST operative constipation' reason for change: Data Entry Error | Riley King (b) (4) | 22 Dec 2020 22:01:41 |
| User entered 'Post op constipation' | Riley King (b) (4) | 22 Dec 2020 21:55:00 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:03:08

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:17 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered '17.2' | Riley King (b) (4) | 22 Dec 2020 21:55:00 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:03:08

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:17 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'mg (mg)' | Riley King (b) (4) | 22 Dec 2020 21:55:00 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:03:08

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:17 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered empty. | Riley King (b) (4) | 22 Dec 2020 21:55:00 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:03:08

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:17 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'once daily (QD)' | Riley King (b) (4) | 22 Dec 2020 21:55:00 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:03:08

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:17 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered empty. | Riley King (b) (4) | 22 Dec 2020 21:55:00 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:03:08

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:17 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'Oral (ORAL)' | Riley King (b) (4) | 22 Dec 2020 21:55:00 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:03:08

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:17 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered empty. | Riley King (b) (4) | 22 Dec 2020 21:55:00 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:03:08

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:17 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered '3 Dec 2020' | Riley King (b) (4) | 22 Dec 2020 21:55:00 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:03:08

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:17 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered '0' | Riley King (b) (4) | 22 Dec 2020 21:55:00 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:03:08

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:17 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'No (N)' | Riley King (b) (4) | 22 Dec 2020 21:55:00 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:03:08

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:17 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered '4 Dec 2020' | Riley King (b) (4) | 22 Dec 2020 21:55:00 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:03:08

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:17 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'No (N)' | Riley King (b) (4) | 22 Dec 2020 21:55:00 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:03:08

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:17 |
| User entered '1' | System | 22 Dec 2020 21:55:00 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:03:08

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:17 |
| User entered '1' | System | 22 Dec 2020 21:55:00 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:03:08

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:17 |
| User entered '804 (804)' | System | 22 Dec 2020 21:55:00 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:03:08

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:21 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4) | 22 Jan 2021 19:58:44 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: SOFTENERS, EMOLLIENTS, PRODUCT: DOCUSATE SODIUM, PRODUCTSYNONYM: COLACE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 22 Dec 2020 22:03:47 |
| User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003. | (b) (4) | 22 Dec 2020 22:03:47 |
| Data point term sent to Coder | System | 22 Dec 2020 22:02:42 |
| Coding entries removed. | Riley King (b) (4) | 22 Dec 2020 22:01:49 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: SOFTENERS, EMOLLIENTS, PRODUCT: DOCUSATE SODIUM, PRODUCTSYNONYM: COLACE - version WHODrug-Global-B3\\202003. | (b) (4) | 22 Dec 2020 21:57:51 |
| User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 22 Dec 2020 21:57:51 |
| Data point term sent to Coder | System | 22 Dec 2020 21:56:33 |
| User entered 'Colace' | Riley King (b) (4) | 22 Dec 2020 21:55:44 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:03:08

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:21 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'No (N)' | Riley King (b) (4) | 22 Dec 2020 21:55:44 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:03:08

[Indication](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:21 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'POST operative constipation' reason for change: Data Entry Error | Riley King (b) (4) | 22 Dec 2020 22:01:49 |
| User entered 'Post op constipation' | Riley King (b) (4) | 22 Dec 2020 21:55:44 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:03:08

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:21 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered '100' | Riley King (b) (4) | 22 Dec 2020 21:55:44 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:03:08

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:21 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'mg (mg)' | Riley King (b) (4) | 22 Dec 2020 21:55:44 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:03:08

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:21 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered empty. | Riley King (b) (4) | 22 Dec 2020 21:55:44 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:03:08

[Frequency](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:21 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'twice daily (BID)' | Riley King (b) (4) | 22 Dec 2020 21:55:44 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:03:08

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:21 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered empty. | Riley King (b) (4) | 22 Dec 2020 21:55:44 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:03:08

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:21 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'Oral (ORAL)' | Riley King (b) (4) | 22 Dec 2020 21:55:44 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:03:08

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:21 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered empty. | Riley King (b) (4) | 22 Dec 2020 21:55:44 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:03:08

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:21 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered '3 Dec 2020' | Riley King (b) (4) | 22 Dec 2020 21:55:44 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:03:08

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:21 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered '0' | Riley King (b) (4) | 22 Dec 2020 21:55:44 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:03:08

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:21 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'No (N)' | Riley King (b) (4) | 22 Dec 2020 21:55:44 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:03:08

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:21 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered '4 Dec 2020' | Riley King (b) (4) | 22 Dec 2020 21:55:44 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:03:08

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:21 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'No (N)' | Riley King (b) (4) | 22 Dec 2020 21:55:44 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:03:08

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:21 |
| User entered '2' | System | 22 Dec 2020 21:55:44 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:03:08

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:21 |
| User entered '1' | System | 22 Dec 2020 21:55:44 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:03:08

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:21 |
| User entered '804 (804)' | System | 22 Dec 2020 21:55:44 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:03:08

Name of Medication

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:24 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: SALICYLIC ACID AND DERIVATIVES, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ECOTRIN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 22 Dec 2020 22:03:47 |
| User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003. | (b) (4) | 22 Dec 2020 22:03:47 |
| Data point term sent to Coder | System | 22 Dec 2020 22:02:42 |
| Coding entries removed. | Riley King (b) (4) | 22 Dec 2020 22:02:14 |
| | (b) (4) | |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: SALICYLIC ACID AND DERIVATIVES, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ECOTRIN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 22 Dec 2020 21:58:54 |
| User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003. | (b) (4) | 22 Dec 2020 21:58:54 |
| Data point term sent to Coder | System | 22 Dec 2020 21:56:33 |
| User entered 'Ecotrin(aspirin)' | Riley King (b) (4) | 22 Dec 2020 21:56:32 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:03:08

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:24 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'No (N)' | Riley King (b) (4) | 22 Dec 2020 21:56:32 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:03:08

[Indication](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:24 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'WORSENING osteoarthritis right knee' reason for change: Data Entry Error | Riley King (b) (4) | 22 Dec 2020 22:02:14 |
| User entered 'Worsening OA R knee' | (b) (4) | |
| | Riley King (b) (4) | 22 Dec 2020 21:56:32 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:03:08

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:24 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered '81' | Riley King (b) (4) | 22 Dec 2020 21:56:32 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:03:08

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:24 |
| User signature succeeded. | Troy Holdeman (b) (4) (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'mg (mg)' | Riley King (b) (4) (b) (4) | 22 Dec 2020 21:56:32 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:03:08

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:24 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered empty. | Riley King (b) (4) | 22 Dec 2020 21:56:32 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:03:08

[Frequency](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:24 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'twice daily (BID)' | Riley King (b) (4) | 22 Dec 2020 21:56:32 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:03:08

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:24 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered empty. | Riley King (b) (4) | 22 Dec 2020 21:56:32 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:03:08

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:24 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'Oral (ORAL)' | Riley King (b) (4) | 22 Dec 2020 21:56:32 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:03:08

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:24 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered empty. | Riley King (b) (4) | 22 Dec 2020 21:56:32 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:03:08

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:24 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered '4 Dec 2020' | Riley King (b) (4) | 22 Dec 2020 21:56:32 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:03:08

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:24 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered '0' | Riley King (b) (4) | 22 Dec 2020 21:56:32 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:03:08

[Ongoing?](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:24 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 30 Mar 2021 19:56:27 |
| 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), (b) (6) | 11 Feb 2021 09:35:28 |
| 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 'reconciled ' (Site from DM). | Riley King (b) (4) | 10 Feb 2021 15:58:21 |
| DataPoint Un-verified. | Riley King (b) (4) | 10 Feb 2021 15:58:13 |
| User entered 'No (N)' reason for change: Per Query Resolution | Riley King (b) (4) | 10 Feb 2021 15:58:13 |
| 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) | 28 Jan 2021 05:21:39 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'Yes (Y)' | Riley King (b) (4) | 22 Dec 2020 21:56:32 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:03:08

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:24 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 30 Mar 2021 19:56:27 |
| DataPoint Un-verified. | Riley King (b) (4) | 10 Feb 2021 15:58:13 |
| User entered '4 Dec 2020' reason for change: Per Query Resolution | Riley King (b) (4) | 10 Feb 2021 15:58:13 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered empty. | Riley King (b) (4) | 22 Dec 2020 21:56:32 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:03:08

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:24 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'No (N)' | Riley King (b) (4) | 22 Dec 2020 21:56:32 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:03:08

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:24 |
| User entered '2' | System | 22 Dec 2020 21:56:32 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:03:08

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:24 |
| User entered '1' | System | 22 Dec 2020 21:56:32 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:03:08

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:24 |
| User entered '804 (804)' | System | 22 Dec 2020 21:56:32 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:03:08

Name of Medication

| Audit | User | Time (GMT) |
|--|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:30 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| User coded data point as ATC: DERMATOLOGICALS, ATC: ANTIFUNGALS FOR DERMATOLOGICAL USE, ATC: ANTIFUNGALS FOR TOPICAL USE, ATC: ANTIBIOTICS, PRODUCT: NYSTATIN;ZINC OXIDE, PRODUCTSYNONYM: NOZIN - version WHODrug-Global-B3\\202003. | (b) (4) Coder Import (b) (4) (b) (4) | 17 Mar 2021 11:30:41 |
| User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 17 Mar 2021 11:30:41 |
| Data point term sent to Coder | System | 10 Mar 2021 16:15:40 |
| Data point term sent to Coder | System | 10 Feb 2021 16:01:32 |
| Coding entries removed. | Riley King (b) (4) | 10 Feb 2021 16:01:21 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: OTHER NASAL PREPARATIONS, PRODUCT: ETHANOL, PRODUCTSYNONYM: NOZIN NASAL SANITIZER - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 23 Dec 2020 00:26:51 |
| User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 23 Dec 2020 00:26:51 |
| Data point term sent to Coder | System | 22 Dec 2020 21:59:37 |
| Data point term sent to Coder | System | 22 Dec 2020 21:57:36 |
| User entered 'Nozin nasal swab' | Riley King (b) (4) (b) (4) | 22 Dec 2020 21:57:27 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:03:08

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:30 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 30 Mar 2021 19:56:04 |
| DataPoint Un-verified. | Riley King (b) (4) | 10 Mar 2021 16:14:53 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Riley King (b) (4) | 10 Mar 2021 16:14:53 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'No (N)' | Riley King (b) (4) | 22 Dec 2020 21:57:27 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:03:08

[Indication](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:30 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 30 Mar 2021 19:56:08 |
| User closed query 'Per DM CLR Re-query: Per response reconciled, however "Infection prophylaxis" is not reported on AE or MH Page . kindly review and amend as appropriate else clarify.' (Site from DM). | (b) (4), (b) (6) | 18 Mar 2021 02:13:06 |
| Query 'Per DM CLR Re-query: Per response reconciled, however "Infection prophylaxis" is not reported on AE or MH Page . kindly review and amend as appropriate else clarify.' answered with 'see word prophylaxis' (Site from DM). | marissa Mueller (b) (4) | 16 Mar 2021 15:24:00 |
| User opened query 'Per DM CLR Re-query: Per response reconciled, however "Infection prophylaxis" is not reported on AE or MH Page . kindly review and amend as appropriate else clarify.' (Site from DM). | (b) (4), (b) (6) | 12 Mar 2021 02:14:50 |
| User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat, rather than the drug class or action of the medication. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM). | (b) (4), (b) (6) | 12 Mar 2021 02:12:24 |
| Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat, rather than the drug class or action of the medication. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' answered with 'reconciled ' (Site from DM). | Riley King (b) (4) | 10 Mar 2021 16:15:14 |
| DataPoint Un-verified. | Riley King (b) (4) | 10 Mar 2021 16:14:53 |
| User entered 'INFECTION prophylaxis' reason for change: Per Query Resolution | Riley King (b) (4) | 10 Mar 2021 16:14:53 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:03:08

[Indication](#)

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat, rather than the drug class or action of the medication. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM). DataPoint Verified. | (b) (4), (b) (6) | 07 Mar 2021 11:33:20 |
| | (b) (4), (b) (6) | 01 Mar 2021 17:23:45 |
| User closed query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM). | (b) (4), (b) (6) | 11 Feb 2021 13:53:05 |
| Query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' | Riley King (b) (4) | 10 Feb 2021 16:01:28 |
| ' answered with 'reconciled' (Site from DM). DataPoint Un-verified. | (b) (4) | |
| | Riley King (b) (4) | 10 Feb 2021 16:01:21 |
| User entered 'Infection control' reason for change: Per Query Resolution | (b) (4) | |
| | Riley King (b) (4) | 10 Feb 2021 16:01:21 |
| User opened query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM). DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 05:34:27 |
| | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 22 Dec 2020 21:58:39 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 22 Dec 2020 21:58:39 |
| User entered 'Worsening osteoarthritis right knee' reason for change: Data Entry Error | Riley King (b) (4) | 22 Dec 2020 21:58:39 |
| | (b) (4) | |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 22 Dec 2020 21:57:27 |

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:03:08

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------|----------------------|
| User entered empty. | Riley King (b) (4) (b) (4) | 22 Dec 2020 21:57:27 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:03:08

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:30 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered '1' | Riley King (b) (4) | 22 Dec 2020 21:57:27 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:03:08

[Dose unit](#)

| Audit | User | Time (GMT) |
|------------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:30 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'Other (OTHER)' | Riley King (b) (4) | 22 Dec 2020 21:57:27 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:03:08

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:30 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'Swab' | Riley King (b) (4) | 22 Dec 2020 21:57:27 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:03:08

[Frequency](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:30 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'twice daily (BID)' | Riley King (b) (4) | 22 Dec 2020 21:57:27 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:03:08

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:30 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered empty. | Riley King (b) (4) | 22 Dec 2020 21:57:27 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:03:08

[Route of administration](#)

| Audit | User | Time (GMT) |
|------------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:30 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'Nasal (NASAL)' | Riley King (b) (4) | 22 Dec 2020 21:57:27 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:03:08

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:30 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered empty. | Riley King (b) (4) | 22 Dec 2020 21:57:27 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:03:08

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:30 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered '3 Dec 2020' | Riley King (b) (4) | 22 Dec 2020 21:57:27 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:03:08

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:30 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered '0' | Riley King (b) (4) | 22 Dec 2020 21:57:27 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:03:08

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:30 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'No (N)' | Riley King (b) (4) | 22 Dec 2020 21:57:27 |
| | (b) (4) | |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:03:08

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:30 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered '3 Dec 2020' | Riley King (b) (4) | 22 Dec 2020 21:57:27 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:03:08

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:30 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 19:58:44 |
| User entered 'No (N)' | Riley King (b) (4) | 22 Dec 2020 21:57:27 |
| | (b) (4) | |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:03:08

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:30 |
| User entered '2' | System | 22 Dec 2020 21:57:27 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:03:08

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:30 |
| User entered '1' | System | 22 Dec 2020 21:57:27 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:03:08

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:26:30 |
| User entered '804 (804)' | System | 22 Dec 2020 21:57:27 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:03:08

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 30 Mar 2021 19:56:27 |
| | | |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: AMITRIPTYLINE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 12 Mar 2021 01:33:00 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 12 Mar 2021 01:33:00 |
| | (b) (4) | |
| Data point term sent to Coder | System | 10 Mar 2021 16:02:13 |
| User entered 'AMITRIPTYLINE' | Janna Martinez (b) (4) | 10 Mar 2021 16:01:51 |
| | | |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:03:08

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 30 Mar 2021 19:56:27 |
| | | |
| User entered 'No (N)' | Janna Martinez (b) (4) | 10 Mar 2021 16:01:51 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:03:08

[Indication](#)

| Audit | User | Time (GMT) |
|--------------------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 30 Mar 2021 19:56:27 |
| | | |
| User entered 'INTERSTITIAL CYSTITIS' | Janna Martinez (b) (4) | 10 Mar 2021 16:01:51 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:03:08

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 30 Mar 2021 19:56:27 |
| | | |
| User entered '25' | Janna Martinez (b) (4) | 10 Mar 2021 16:01:51 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:03:08

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 30 Mar 2021 19:56:27 |
| | | |
| User entered 'mg (mg)' | Janna Martinez (b) (4) | 10 Mar 2021 16:01:51 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:03:08

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 30 Mar 2021 19:56:27 |
| | | |
| User entered empty. | Janna Martinez (b) (4) | 10 Mar 2021 16:01:51 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:03:08

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 30 Mar 2021 19:56:27 |
| | | |
| User entered 'once daily (QD)' | Janna Martinez (b) (4) | 10 Mar 2021 16:01:51 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:03:08

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 30 Mar 2021 19:56:27 |
| | | |
| User entered empty. | Janna Martinez (b) (4) | 10 Mar 2021 16:01:51 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:03:08

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 30 Mar 2021 19:56:27 |
| | | |
| User entered 'Oral (ORAL)' | Janna Martinez (b) (4) | 10 Mar 2021 16:01:51 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:03:08

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 30 Mar 2021 19:56:27 |
| | | |
| User entered empty. | Janna Martinez (b) (4) | 10 Mar 2021 16:01:51 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:03:08

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 30 Mar 2021 19:56:27 |
| | | |
| User entered '25 Nov 2020' | Janna Martinez (b) (4) | 10 Mar 2021 16:01:51 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:03:08

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 30 Mar 2021 19:56:27 |
| | | |
| User entered '0' | Janna Martinez (b) (4) | 10 Mar 2021 16:01:51 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:03:08

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 30 Mar 2021 19:56:27 |
| | | |
| User entered 'Yes (Y)' | Janna Martinez (b) (4) | 10 Mar 2021 16:01:51 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:03:08

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 30 Mar 2021 19:56:27 |
| | | |
| User entered empty. | Janna Martinez (b) (4) | 10 Mar 2021 16:01:51 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:03:08

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 30 Mar 2021 19:56:27 |
| | | |
| User entered 'No (N)' | Janna Martinez (b) (4) | 10 Mar 2021 16:01:51 |
| | (b) (4) | |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:03:08

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 10 Mar 2021 16:01:51 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:03:08

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 10 Mar 2021 16:01:51 |

US3062128

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:03:08

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 10 Mar 2021 16:01:51 |

US3062128

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:03:08

[Were any concomitant procedures performed?](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 07:16:40 |
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 17:50:49 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Jeri King (b) (4) | 09 Dec 2020 19:39:47 |
| User entered 'No (N)' | marissa Mueller (b) (4) | 01 Sep 2020 23:07:45 |
| | (b) (4) | |

US3062128

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:03:08

Procedure/Surgery date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 17:51:14 |
| User entered '03 Dec 2020' | Jeri King (b) (4) | 09 Dec 2020 19:40:05 |

US3062128

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:03:08

[Procedure/Surgery](#)

| Audit | User | Time (GMT) |
|---------------------------------------|-----------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 17:51:14 |
| | | |
| User entered 'Right Knee Replacement' | Jeri King (b) (4) | 09 Dec 2020 19:40:05 |
| | | |

US3062128

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:03:08

[Indication](#)

| Audit | User | Time (GMT) |
|-----------------------------------|----------------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 17:51:14 |
| User entered 'Adverse Event (AE)' | Jeri King (b) (4) | 09 Dec 2020 19:40:05 |

US3062128

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:03:08

If indication is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) (b) (4) | 02 Apr 2021 20:33:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Jan 2021 17:51:14 |
| User entered empty. | Jeri King (b) (4) | 09 Dec 2020 19:40:05 |

US3062128

Folder: SAE USA-US090-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:08

[SAEID](#)

| Audit | User | Time (GMT) |
|---------------------------------------|-----------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:48:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Dec 2020 21:12:03 |
| User entered | System | 10 Dec 2020 21:11:20 |
| 'USA-US090-2020-MRNA-1273-P301000010' | | |

US3062128

Folder: SAE USA-US090-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:08

Serious

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:48:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Dec 2020 21:12:03 |
| User entered 'Yes (Y)' | System | 10 Dec 2020 21:11:20 |

US3062128

Folder: SAE USA-US090-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:08

Death

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:48:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Dec 2020 21:12:03 |
| User entered 'No (N)' | System | 10 Dec 2020 21:11:20 |

US3062128

Folder: SAE USA-US090-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:08

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:48:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Dec 2020 21:12:03 |
| User entered 'No (N)' | System | 10 Dec 2020 21:11:20 |

US3062128

Folder: SAE USA-US090-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:08

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:48:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Dec 2020 21:12:03 |
| User entered 'Yes (Y)' | System | 10 Dec 2020 21:11:20 |

US3062128

Folder: SAE USA-US090-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:08

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:48:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Dec 2020 21:12:03 |
| User entered 'No (N)' | System | 10 Dec 2020 21:11:20 |

US3062128

Folder: SAE USA-US090-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:08

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:48:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Dec 2020 21:12:03 |
| User entered 'No (N)' | System | 10 Dec 2020 21:11:20 |

US3062128

Folder: SAE USA-US090-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:08

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:48:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Dec 2020 21:12:03 |
| User entered 'No (N)' | System | 10 Dec 2020 21:11:20 |

US3062128

Folder: SAE USA-US090-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:08

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:48:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Dec 2020 21:12:03 |
| User entered 'Richard' | System | 10 Dec 2020 21:11:20 |

US3062128

Folder: SAE USA-US090-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:08

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:48:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Dec 2020 21:12:03 |
| User entered 'Glover' | System | 10 Dec 2020 21:11:20 |

US3062128

Folder: SAE USA-US090-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:08

Site Address: Street

| Audit | User | Time (GMT) |
|---------------------------------------|-----------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:48:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Dec 2020 21:12:03 |
| User entered '700 Medical Center Dr.' | System | 10 Dec 2020 21:11:20 |

US3062128

Folder: SAE USA-US090-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:08

Site Address: City

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:48:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Dec 2020 21:12:03 |
| User entered 'Newton' | System | 10 Dec 2020 21:11:20 |

US3062128

Folder: SAE USA-US090-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:08

Site Address: State

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:48:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Dec 2020 21:12:03 |
| User entered 'KS' | System | 10 Dec 2020 21:11:20 |

US3062128

Folder: SAE USA-US090-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:08

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:48:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Dec 2020 21:12:03 |
| User entered '67114' | System | 10 Dec 2020 21:11:20 |

US3062128

Folder: SAE USA-US090-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:08

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Dec 2020 15:18:14 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:48:17 |
| User entered 'US' | System | 10 Dec 2020 21:12:10 |

US3062128

Folder: SAE USA-US090-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:08

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '2' | System | 23 Dec 2020 15:18:35 |
| User entered '1' | System | 10 Dec 2020 21:12:10 |

US3062128

Folder: SAE USA-US090-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:08

[SAEID](#)

| Audit | User | Time (GMT) |
|---------------------------------------|-----------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:48:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Dec 2020 21:12:03 |
| User entered | System | 10 Dec 2020 21:11:20 |
| 'USA-US090-2020-MRNA-1273-P301000010' | | |

US3062128

Folder: SAE USA-US090-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:08

Serious

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:48:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Dec 2020 21:12:03 |
| User entered 'Yes (Y)' | System | 10 Dec 2020 21:11:20 |

US3062128

Folder: SAE USA-US090-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:08

Death

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:48:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Dec 2020 21:12:03 |
| User entered 'No (N)' | System | 10 Dec 2020 21:11:20 |

US3062128

Folder: SAE USA-US090-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:08

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:48:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Dec 2020 21:12:03 |
| User entered 'No (N)' | System | 10 Dec 2020 21:11:20 |

US3062128

Folder: SAE USA-US090-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:08

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:48:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Dec 2020 21:12:03 |
| User entered 'Yes (Y)' | System | 10 Dec 2020 21:11:20 |

US3062128

Folder: SAE USA-US090-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:08

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:48:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Dec 2020 21:12:03 |
| User entered 'No (N)' | System | 10 Dec 2020 21:11:20 |

US3062128

Folder: SAE USA-US090-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:08

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:48:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Dec 2020 21:12:03 |
| User entered 'No (N)' | System | 10 Dec 2020 21:11:20 |

US3062128

Folder: SAE USA-US090-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:08

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:48:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Dec 2020 21:12:03 |
| User entered 'No (N)' | System | 10 Dec 2020 21:11:20 |

US3062128

Folder: SAE USA-US090-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:08

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:48:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Dec 2020 21:12:03 |
| User entered 'Richard' | System | 10 Dec 2020 21:11:20 |

US3062128

Folder: SAE USA-US090-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:08

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:48:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Dec 2020 21:12:03 |
| User entered 'Glover' | System | 10 Dec 2020 21:11:20 |

US3062128

Folder: SAE USA-US090-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:08

Site Address: Street

| Audit | User | Time (GMT) |
|---------------------------------------|-----------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:48:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Dec 2020 21:12:03 |
| User entered '700 Medical Center Dr.' | System | 10 Dec 2020 21:11:20 |

US3062128

Folder: SAE USA-US090-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:08

Site Address: City

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:48:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Dec 2020 21:12:03 |
| User entered 'Newton' | System | 10 Dec 2020 21:11:20 |

US3062128

Folder: SAE USA-US090-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:08

Site Address: State

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:48:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Dec 2020 21:12:03 |
| User entered 'KS' | System | 10 Dec 2020 21:11:20 |

US3062128

Folder: SAE USA-US090-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:08

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:48:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Dec 2020 21:12:03 |
| User entered '67114' | System | 10 Dec 2020 21:11:20 |

US3062128

Folder: SAE USA-US090-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:08

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Dec 2020 15:18:14 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:48:17 |
| User entered 'US' | System | 10 Dec 2020 21:12:10 |

US3062128

Folder: SAE USA-US090-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:08

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '2' | System | 23 Dec 2020 15:18:35 |
| User entered '1' | System | 10 Dec 2020 21:12:10 |

US3062128

Folder: SAE USA-US090-2020-MRNA-1273-P301000010

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:03:08

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:48:17 |
| User entered '10/Dec/2020 21:12' | System | 10 Dec 2020 21:12:10 |

US3062128

Folder: SAE USA-US090-2020-MRNA-1273-P301000010

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:03:08

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.

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Dec 2020 15:18:14 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:48:17 |
| User entered 'I' | (b) (4), (b) (6) | 10 Dec 2020 21:12:10 |

US3062128

Folder: SAE USA-US090-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:08

[SAEID](#)

| Audit | User | Time (GMT) |
|---------------------------------------|-----------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:48:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Dec 2020 21:12:03 |
| User entered | System | 10 Dec 2020 21:11:20 |
| 'USA-US090-2020-MRNA-1273-P301000010' | | |

US3062128

Folder: SAE USA-US090-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:08

Serious

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:48:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Dec 2020 21:12:03 |
| User entered 'Yes (Y)' | System | 10 Dec 2020 21:11:20 |

US3062128

Folder: SAE USA-US090-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:08

Death

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:48:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Dec 2020 21:12:03 |
| User entered 'No (N)' | System | 10 Dec 2020 21:11:20 |

US3062128

Folder: SAE USA-US090-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:08

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:48:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Dec 2020 21:12:03 |
| User entered 'No (N)' | System | 10 Dec 2020 21:11:20 |

US3062128

Folder: SAE USA-US090-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:08

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:48:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Dec 2020 21:12:03 |
| User entered 'Yes (Y)' | System | 10 Dec 2020 21:11:20 |

US3062128

Folder: SAE USA-US090-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:08

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:48:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Dec 2020 21:12:03 |
| User entered 'No (N)' | System | 10 Dec 2020 21:11:20 |

US3062128

Folder: SAE USA-US090-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:08

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:48:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Dec 2020 21:12:03 |
| User entered 'No (N)' | System | 10 Dec 2020 21:11:20 |

US3062128

Folder: SAE USA-US090-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:08

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:48:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Dec 2020 21:12:03 |
| User entered 'No (N)' | System | 10 Dec 2020 21:11:20 |

US3062128

Folder: SAE USA-US090-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:08

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:48:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Dec 2020 21:12:03 |
| User entered 'Richard' | System | 10 Dec 2020 21:11:20 |

US3062128

Folder: SAE USA-US090-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:08

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:48:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Dec 2020 21:12:03 |
| User entered 'Glover' | System | 10 Dec 2020 21:11:20 |

US3062128

Folder: SAE USA-US090-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:08

Site Address: Street

| Audit | User | Time (GMT) |
|---------------------------------------|-----------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:48:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Dec 2020 21:12:03 |
| User entered '700 Medical Center Dr.' | System | 10 Dec 2020 21:11:20 |

US3062128

Folder: SAE USA-US090-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:08

Site Address: City

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:48:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Dec 2020 21:12:03 |
| User entered 'Newton' | System | 10 Dec 2020 21:11:20 |

US3062128

Folder: SAE USA-US090-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:08

[Site Address: State](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:48:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Dec 2020 21:12:03 |
| User entered 'KS' | System | 10 Dec 2020 21:11:20 |

US3062128

Folder: SAE USA-US090-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:08

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:48:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Dec 2020 21:12:03 |
| User entered '67114' | System | 10 Dec 2020 21:11:20 |

US3062128

Folder: SAE USA-US090-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:08

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Dec 2020 15:18:14 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Dec 2020 15:48:17 |
| User entered 'US' | System | 10 Dec 2020 21:12:10 |

US3062128

Folder: SAE USA-US090-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:08

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '2' | System | 23 Dec 2020 15:18:35 |
| User entered '1' | System | 10 Dec 2020 21:12:10 |

US3062128

Folder: SAE USA-US090-2020-MRNA-1273-P301000010

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:03:08

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 30 Mar 2021 19:51:47 |
| User entered '23/Dec/2020 10:18' | System | 23 Dec 2020 15:18:35 |

US3062128

Folder: SAE USA-US090-2020-MRNA-1273-P301000010

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:03:08

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.

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Troy Holdeman (b) (4) | 02 Apr 2021 20:33:50 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 30 Mar 2021 19:51:47 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Dec 2020 15:18:53 |
| User entered 'I' | (b) (4), (b) (6) | 23 Dec 2020 15:18:35 |