

US3722338 (Prod: Keystone VitaLink Research - Greenville - PPDS)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:26:23

All time stamps listed in this document are displayed in GMT

US3722338

Form: Participant Creation

Data signed: (b) (4) 28 Apr 2021 21:56:11

Generated On: 10 Jun 2021 09:26:23

Participant ID

US3722338

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

US3722338

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 09 Mar 2021 11:33:22

Generated On: 10 Jun 2021 09:26:23

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 20 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 |

US3722338

Folder: Screening

Form: Demographics

Data signed: (b) (4) 09 Mar 2021 11:33:22

Generated On: 10 Jun 2021 09:26:23

| | |
|---|--|
| Date of Birth (MMM yyyy) | (b) (6) 1947 |
| Age | 73 |
| Age Units | YEARS |
| Age (Derived) | 73 |
| Sex | Female <input type="radio"/> Male <input checked="" type="radio"/> |
| Ethnicity | Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/> |
| Race (Check All That Apply) | |
| White | True |
| Black | False |
| Asian | False |
| American Indian or Alaska Native | False |
| Native Hawaiian or other Pacific Islander | False |
| Other | False |
| If race is Other, specify _____ | |
| Unknown | False |
| Not reported | False |

US3722338

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 09 Mar 2021 11:33:22

Generated On: 10 Jun 2021 09:26:23

| | |
|---|--|
| Date of Informed Consent (<i>dd MMM yyyy</i>) | 20 AUG 2020 |
| Month and Year of Informed Consent (derived) | AUG 2020 |
| Year of Informed Consent (derived) | 2020 |
| Protocol Version | Amendment 1 <input type="radio"/> |
| | Amendment 2 <input checked="" type="radio"/> |
| | Amendment 3 <input type="radio"/> |
| | Amendment 4 <input type="radio"/> |
| | Amendment 5 <input type="radio"/> |
| Was participant enrolled in the study? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| If No, indicate reason for screen fail | Withdrew Consent <input type="radio"/> |
| | Inclusion/Exclusion <input type="radio"/> |
| | Cohort Full <input type="radio"/> |
| | Other <input type="radio"/> |
| If reason for screen fail is Other, specify | |
| Was this participant screened previously? | Yes <input type="radio"/> |
| | No <input checked="" type="radio"/> |
| If Yes, previous participant number | |
| Enrollment Trigger | 1 |

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 09 Mar 2021 11:33:22

Generated On: 10 Jun 2021 09:26:23

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 28 Apr 2021 21:56:15

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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) 28 Apr 2021 21:56:15

Generated On: 10 Jun 2021 09:26:23

| | |
|---|--|
| Condition | DIABETES 2 |
| Start date (dd MMM yyyy) | UN UNK 1990 |
| 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 1990 |
| Start Year (derived) | 1990 |
| Stop Month and Year (derived) | |
| Stop Year (derived) | |

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 28 Apr 2021 21:56:15

Generated On: 10 Jun 2021 09:26:23

| | |
|---|--|
| Condition | HYPERTENSION |
| Start date (dd MMM yyyy) | UN UNK 2016 |
| 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 2016 |
| Start Year (derived) | 2016 |
| Stop Month and Year (derived) | _____ |
| Stop Year (derived) | _____ |

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 28 Apr 2021 21:56:15

Generated On: 10 Jun 2021 09:26:23

| | |
|---|--|
| Condition | HYPERLIPIDEMIA |
| Start date (dd MMM yyyy) | UN UNK 2016 |
| 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 2016 |
| Start Year (derived) | 2016 |
| Stop Month and Year (derived) | |
| Stop Year (derived) | |

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 28 Apr 2021 21:56:15

Generated On: 10 Jun 2021 09:26:23

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

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 28 Apr 2021 21:56:15

Generated On: 10 Jun 2021 09:26:23

| | |
|---|--|
| Condition | INSOMNIA |
| Start date (dd MMM yyyy) | UN UNK 2015 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) | |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 2015 |
| Start Year (derived) | 2015 |
| Stop Month and Year (derived) | |
| Stop Year (derived) | |

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 28 Apr 2021 21:56:15

Generated On: 10 Jun 2021 09:26:23

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

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 28 Apr 2021 21:56:15

Generated On: 10 Jun 2021 09:26:23

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

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 28 Apr 2021 21:56:15

Generated On: 10 Jun 2021 09:26:23

| | |
|---|--|
| Condition | DYSPNEA |
| Start date (dd MMM yyyy) | UN UNK 2016 |
| 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 2016 |
| Start Year (derived) | 2016 |
| Stop Month and Year (derived) | _____ |
| Stop Year (derived) | _____ |

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 28 Apr 2021 21:56:15

Generated On: 10 Jun 2021 09:26:23

| | |
|---|--|
| Condition | SEASONAL ALLERGIES |
| Start date (dd MMM yyyy) | UN UNK 2016 |
| 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 2016 |
| Start Year (derived) | 2016 |
| Stop Month and Year (derived) | |
| Stop Year (derived) | |

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 28 Apr 2021 21:56:15

Generated On: 10 Jun 2021 09:26:23

| | |
|---|--|
| Condition | OSTEOARTHRITIS ARTHRITIS IN BILATERAL KNEES |
| Start date (dd MMM yyyy) | UN UNK 2015 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) | |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 2015 |
| Start Year (derived) | 2015 |
| Stop Month and Year (derived) | |
| Stop Year (derived) | |

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 28 Apr 2021 21:56:15

Generated On: 10 Jun 2021 09:26:23

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

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 28 Apr 2021 21:56:15

Generated On: 10 Jun 2021 09:26:23

| | |
|---|--|
| Condition | VARICOSE VEINS |
| Start date (dd MMM yyyy) | UN UNK 2016 |
| 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 2016 |
| Start Year (derived) | 2016 |
| Stop Month and Year (derived) | |
| Stop Year (derived) | |

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 28 Apr 2021 21:56:15

Generated On: 10 Jun 2021 09:26:23

| | |
|---|--|
| Condition | HERNIA LEFT LOWER QUADRANT |
| Start date (dd MMM yyyy) | UN UNK 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) | _____ |

US3722338

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 09 Mar 2021 11:33:22

Generated On: 10 Jun 2021 09:26:23

| | |
|---|--------------------------------------|
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (<i>dd MMM yyyy</i>) | 20 AUG 2020 |
| Time of assessment (<i>00:00-23:59</i>) | 12:05 (24 HR) |
| Vital Signs Date and Time (derived) | 20 AUG 2020 12:05 |
| Height (<i>xxx.x</i>) | 68 in |
| Weight (<i>xxx.x</i>) | 266 lb |
| BMI (<i>xxx.x</i>) | 40.52973 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) 09 Mar 2021 11:33:22

Generated On: 10 Jun 2021 09:26:23

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

20 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 09 Mar 2021 11:33:22

Generated On: 10 Jun 2021 09:26:23

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) 09 Mar 2021 11:33:22

Generated On: 10 Jun 2021 09:26:23

| | |
|--|-------|
| 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) 25 Feb 2021 17:47:46

Generated On: 10 Jun 2021 09:26:23

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

| | |
|--------------------------|-------------|
| Visit date (dd MMM yyyy) | 20 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 |
|------------|--------|

US3722338

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 25 Feb 2021 17:47:46

Generated On: 10 Jun 2021 09:26:23

What was the date of randomization? (dd MMM yyyy) 20 AUG 2020

What was the participant's randomization number? 187125

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

US3722338

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 25 Feb 2021 17:47:46

Generated On: 10 Jun 2021 09:26:23

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

US3722338

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 25 Feb 2021 17:47:46

Generated On: 10 Jun 2021 09:26:23

| | |
|-------------------------------------|--|
| 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) | 20 AUG 2020 |
| Time of assessment (00:00-23:59) | 12:05 (24 HR) |
| Vital Signs Date and Time (derived) | 20 AUG 2020 12:05 |
| Temperature (xxx.x) | 98.5 F |
| Route of measurement | Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 86 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 17 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 140 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 67 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3722338

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 25 Feb 2021 17:47:46

Generated On: 10 Jun 2021 09:26:23

| | |
|-------------------------------------|--|
| 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) | 20 AUG 2020 |
| Time of assessment (00:00-23:59) | 13:35 (24 HR) |
| Vital Signs Date and Time (derived) | 20 AUG 2020 13:35 |
| 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) | 72 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 18 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 133 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 70 mmHg |
| Diastolic Blood Pressure units | MMHG |

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 25 Feb 2021 17:47:46

Generated On: 10 Jun 2021 09:26:23

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) 25 Feb 2021 17:47:46

Generated On: 10 Jun 2021 09:26:23

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) 20 AUG 2020

What was the treatment time? (00:00-23:59) 13:05 (24 HR)

Treatment Date and Time (derived) 20 AUG 2020 13:05

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) 25 Feb 2021 17:47:46

Generated On: 10 Jun 2021 09:26:23

| | |
|------------------------------------|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (dd MMM yyyy) | 20 AUG 2020 |
| Collection time (00:00-23:59) | 12:35 (24 HR) |
| Collection date and time (derived) | 20 AUG 2020 12:35 |

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 25 Feb 2021 17:47:46

Generated On: 10 Jun 2021 09:26:23

| | | | |
|-------------------------------|---------------------------|---------------------------------|------------------------------------|
| Collection date (dd MMM yyyy) | | | 20 AUG 2020 |
| Lab Test | Was the sample collected? | Collection time (00:00 - 23:59) | Collection date and time (derived) |
| Nasopharyngeal Swab 1 | Yes | 12:19 | 20 AUG 2020 12:19 |
| Nasopharyngeal Swab 2 | Yes | 12:19 | 20 AUG 2020 12:19 |

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 25 Feb 2021 17:47:46

Generated On: 10 Jun 2021 09:26:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 AUG 2020 13:37

PC Open Date & Time

20 AUG 2020 13:25

PC Close Date & Time

20 AUG 2020 15:55

US3722338

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☐
No ☐

Please record your **TEMPERATURE** in °F

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 20 AUG 2020 16:50

PC Close Date & Time 21 AUG 2020 11:59

US3722338

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:26:23

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

21 AUG 2020 14:01

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3722338

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 AUG 2020 20:45

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3722338

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:26:23

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

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 AUG 2020 13:28

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3722338

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 AUG 2020 14:29

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3722338

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.3 °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

25 AUG 2020 13:12

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3722338

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:26:23

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

26 AUG 2020 13:06

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3722338

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:26:23

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

20 AUG 2020 13:38

PC Open Date & Time

20 AUG 2020 13:25

PC Close Date & Time

20 AUG 2020 15:55

US3722338

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

20 AUG 2020 16:50

PC Close Date & Time

21 AUG 2020 11:59

US3722338

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:26:23

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

21 AUG 2020 14:02

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3722338

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:26:23

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

22 AUG 2020 20:45

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3722338

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:26:23

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

23 AUG 2020 13:28

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3722338

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:26:23

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

24 AUG 2020 14:29

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3722338

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:26:23

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

25 AUG 2020 13:12

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3722338

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:26:23

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

26 AUG 2020 13:06

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3722338

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:26:23

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 ☐

US3722338

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:26:23

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 20 AUG 2020 13:39 |
| PC Open Date & Time | 20 AUG 2020 13:25 |
| PC Close Date & Time | 20 AUG 2020 15:55 |

US3722338

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:26:23

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 ☐

US3722338

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:26:23

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

20 AUG 2020 16:50

PC Close Date & Time

21 AUG 2020 11:59

US3722338

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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US3722338

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:26:23

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 21 AUG 2020 14:02 |
| PC Open Date & Time | 21 AUG 2020 12:00 |
| PC Close Date & Time | 22 AUG 2020 11:59 |

US3722338

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3722338

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:26:23

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 22 AUG 2020 20:46 |
| PC Open Date & Time | 22 AUG 2020 12:00 |
| PC Close Date & Time | 23 AUG 2020 11:59 |

US3722338

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:26:23

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 ☒

US3722338

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:26:23

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 23 AUG 2020 13:29 |
| PC Open Date & Time | 23 AUG 2020 12:00 |
| PC Close Date & Time | 24 AUG 2020 11:59 |

US3722338

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:26:23

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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US3722338

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:26:23

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 24 AUG 2020 14:30 |
| PC Open Date & Time | 24 AUG 2020 12:00 |
| PC Close Date & Time | 25 AUG 2020 11:59 |

US3722338

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3722338

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:26:23

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 25 AUG 2020 13:13 |
| PC Open Date & Time | 25 AUG 2020 12:00 |
| PC Close Date & Time | 26 AUG 2020 11:59 |

US3722338

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:26:23

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 ☒

US3722338

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:26:23

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 26 AUG 2020 13:07 |
| PC Open Date & Time | 26 AUG 2020 12:00 |
| PC Close Date & Time | 27 AUG 2020 11:59 |

US3722338

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 25 Feb 2021 17:47:46

Generated On: 10 Jun 2021 09:26:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3722338

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 25 Feb 2021 17:47:46

Generated On: 10 Jun 2021 09:26:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722338

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 09 Mar 2021 11:33:22

Generated On: 10 Jun 2021 09:26:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

03 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3722338

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 11:33:22

Generated On: 10 Jun 2021 09:26:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722338

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 25 Feb 2021 17:47:46

Generated On: 10 Jun 2021 09:26:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3722338

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 25 Feb 2021 17:47:46

Generated On: 10 Jun 2021 09:26:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722338

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 25 Feb 2021 17:47:46

Generated On: 10 Jun 2021 09:26:23

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 17 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 |

US3722338

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 25 Feb 2021 17:47:46

Generated On: 10 Jun 2021 09:26:23

| | |
|-------------------------------------|---|
| 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) | 17 SEP 2020 |
| Time of assessment (00:00-23:59) | 09:15 (24 HR) |
| Vital Signs Date and Time (derived) | 17 SEP 2020 09:15 |
| Temperature (xxx.x) | 98 F |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 73 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 16 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 125 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 61 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3722338

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 25 Feb 2021 17:47:46

Generated On: 10 Jun 2021 09:26:23

| | |
|-------------------------------------|---|
| 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) | 17 SEP 2020 |
| Time of assessment (00:00-23:59) | 11:01 (24 HR) |
| Vital Signs Date and Time (derived) | 17 SEP 2020 11:01 |
| Temperature (xxx.x) | 98 F |
| Route of measurement | Oral <input checked="" type="checkbox"/> |
| | Axillary <input type="checkbox"/> |
| | Other <input type="checkbox"/> |
| If Other, specify | |
| Pulse (xxx) | 65 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 18 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 127 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 66 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3722338

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 25 Feb 2021 17:47:46

Generated On: 10 Jun 2021 09:26:23

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

17 SEP 2020

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

US3722338

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 25 Feb 2021 17:47:46

Generated On: 10 Jun 2021 09:26:23

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) 17 SEP 2020

What was the treatment time? (00:00-23:59) 10:31 (24 HR)

Treatment Date and Time (derived) 17 SEP 2020 10:31

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

US3722338

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 25 Feb 2021 17:47:46

Generated On: 10 Jun 2021 09:26:23

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

17 SEP 2020

Collection time (00:00-23:59)

10:00 (24 HR)

Collection date and time (derived)

17 SEP 2020 10:00

US3722338

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 25 Feb 2021 17:47:46

Generated On: 10 Jun 2021 09:26:23

| Collection date (dd MMM yyyy) | | | 17 SEP 2020 |
|-------------------------------|---------------------------|---------------------------------|------------------------------------|
| Lab Test | Was the sample collected? | Collection time (00:00 - 23:59) | Collection date and time (derived) |
| Nasopharyngeal Swab 1 | Yes | 09:57 | 17 SEP 2020 09:57 |
| Nasopharyngeal Swab 2 | Yes | 09:57 | 17 SEP 2020 09:57 |

US3722338

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 25 Feb 2021 17:47:46

Generated On: 10 Jun 2021 09:26:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722338

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:26:23

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

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 SEP 2020 11:01

PC Open Date & Time

17 SEP 2020 10:51

PC Close Date & Time

17 SEP 2020 13:21

US3722338

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.1 °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 | 17 SEP 2020 18:14 |
| PC Open Date & Time | 17 SEP 2020 14:16 |
| PC Close Date & Time | 18 SEP 2020 11:59 |

US3722338

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:26:23

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

97.3 °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

18 SEP 2020 14:54

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3722338

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:26:23

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

97.1 °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

19 SEP 2020 12:07

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3722338

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:26:23

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

97.7 °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

20 SEP 2020 13:06

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3722338

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:26:23

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

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 SEP 2020 14:52

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3722338

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 SEP 2020 12:03

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3722338

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 SEP 2020 12:03

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3722338

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:26:23

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

17 SEP 2020 11:03

PC Open Date & Time

17 SEP 2020 10:51

PC Close Date & Time

17 SEP 2020 13:21

US3722338

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:26:23

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

17 SEP 2020 18:14

PC Open Date & Time

17 SEP 2020 14:16

PC Close Date & Time

18 SEP 2020 11:59

US3722338

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:26:23

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

18 SEP 2020 14:55

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3722338

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:26:23

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

19 SEP 2020 12:07

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3722338

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:26:23

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

20 SEP 2020 13:06

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3722338

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:26:23

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

21 SEP 2020 14:52

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3722338

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:26:23

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

22 SEP 2020 12:03

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3722338

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:26:23

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

23 SEP 2020 12:03

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3722338

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:26:23

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 ☐

US3722338

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:26:23

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 17 SEP 2020 11:03 |
| PC Open Date & Time | 17 SEP 2020 10:51 |
| PC Close Date & Time | 17 SEP 2020 13:21 |

US3722338

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:26:23

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 ☐

US3722338

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:26:23

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 17 SEP 2020 18:14 |
| PC Open Date & Time | 17 SEP 2020 14:16 |
| PC Close Date & Time | 18 SEP 2020 11:59 |

US3722338

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

DAY 2

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3722338

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:26:23

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 18 SEP 2020 14:55 |
| PC Open Date & Time | 18 SEP 2020 12:00 |
| PC Close Date & Time | 19 SEP 2020 11:59 |

US3722338

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:26:23

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 19 SEP 2020 12:07 |
| PC Open Date & Time | 19 SEP 2020 12:00 |
| PC Close Date & Time | 20 SEP 2020 11:59 |

US3722338

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:26:23

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 ☒

US3722338

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:26:23

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 20 SEP 2020 13:07 |
| PC Open Date & Time | 20 SEP 2020 12:00 |
| PC Close Date & Time | 21 SEP 2020 11:59 |

US3722338

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:26:23

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 21 SEP 2020 14:53 |
| PC Open Date & Time | 21 SEP 2020 12:00 |
| PC Close Date & Time | 22 SEP 2020 11:59 |

US3722338

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3722338

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:26:23

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 22 SEP 2020 12:04 |
| PC Open Date & Time | 22 SEP 2020 12:00 |
| PC Close Date & Time | 23 SEP 2020 11:59 |

US3722338

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:26:23

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)

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US3722338

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:26:23

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

US3722338

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 25 Feb 2021 17:47:46

Generated On: 10 Jun 2021 09:26:23

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

US3722338

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 25 Feb 2021 17:47:46

Generated On: 10 Jun 2021 09:26:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722338

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 25 Feb 2021 17:47:46

Generated On: 10 Jun 2021 09:26:23

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 8 OCT 2020

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

Comments MULTIPLE ATTEMPTS MADE;
BUT ULTIMATELY
If Contact Not Made, please provide Comments UNSUCCESSFUL.

US3722338

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 25 Feb 2021 17:47:46

Generated On: 10 Jun 2021 09:26:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722338

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 25 Feb 2021 17:47:46

Generated On: 10 Jun 2021 09:26:23

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 08 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3722338

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 25 Feb 2021 17:47:46

Generated On: 10 Jun 2021 09:26:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722338

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 25 Feb 2021 17:47:46

Generated On: 10 Jun 2021 09:26:23

Was this visit performed? Yes ☐
No ☒

Visit date (dd MMM yyyy)

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

Folder OID VISIT3

US3722338

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 25 Feb 2021 17:47:46

Generated On: 10 Jun 2021 09:26:23

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3722338

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 25 Feb 2021 17:47:46

Generated On: 10 Jun 2021 09:26:23

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.

US3722338

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 25 Feb 2021 17:47:46

Generated On: 10 Jun 2021 09:26:23

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3722338

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 25 Feb 2021 17:47:46

Generated On: 10 Jun 2021 09:26:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

| TIMEPOINT | DAY 64 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="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"/> |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

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

Date and time of submission

Patient Cloud Open Date & Time

20 OCT 2020 00:01

Patient Cloud Close Date & Time

24 OCT 2020 23:59

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

| TIMEPOINT | DAY 71 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <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"/> |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

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

Date and time of submission

Patient Cloud Open Date & Time

27 OCT 2020 00:01

Patient Cloud Close Date & Time

31 OCT 2020 23:59

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

03 NOV 2020 00:01

Patient Cloud Close Date & Time

07 NOV 2020 23:59

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

| 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 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"/> |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

| TIMEPOINT | DAY 96 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

25 NOV 2020 23:59

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

| TIMEPOINT | DAY 103 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <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"/> |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2020 23:59

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

| TIMEPOINT | DAY 110 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="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"/> |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

[Patient Cloud Close Date & Time](#)

09 DEC 2020 23:59

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 12 DEC 2020 00:01 |
| Patient Cloud Close Date & Time | 16 DEC 2020 23:59 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

| TIMEPOINT | DAY 124 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input checked="" type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input checked="" type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/> |
| Date and time of submission | 23 DEC 2020 08:35:50 |
| Patient Cloud Open Date & Time | 19 DEC 2020 00:01 |
| Patient Cloud Close Date & Time | 23 DEC 2020 23:59 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

26 DEC 2020 02:04:50

Patient Cloud Open Date & Time

26 DEC 2020 00:01

Patient Cloud Close Date & Time

30 DEC 2020 23:59

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

02 JAN 2021 00:33:07

Patient Cloud Open Date & Time

02 JAN 2021 00:01

Patient Cloud Close Date & Time

06 JAN 2021 23:59

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

11 JAN 2021 00:16:31

Patient Cloud Open Date & Time

09 JAN 2021 00:01

Patient Cloud Close Date & Time

13 JAN 2021 23:59

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

16 JAN 2021 00:13:06

Patient Cloud Open Date & Time

16 JAN 2021 00:01

Patient Cloud Close Date & Time

20 JAN 2021 23:59

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

23 JAN 2021 00:02:09

Patient Cloud Open Date & Time

23 JAN 2021 00:01

Patient Cloud Close Date & Time

27 JAN 2021 23:59

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

30 JAN 2021 04:37:39

Patient Cloud Open Date & Time

30 JAN 2021 00:01

Patient Cloud Close Date & Time

03 FEB 2021 23:59

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

06 FEB 2021 00:02:24

Patient Cloud Open Date & Time

06 FEB 2021 00:01

Patient Cloud Close Date & Time

10 FEB 2021 23:59

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

15 FEB 2021 17:48:56

Patient Cloud Open Date & Time

13 FEB 2021 00:01

Patient Cloud Close Date & Time

17 FEB 2021 23:59

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

20 FEB 2021 11:35:09

Patient Cloud Open Date & Time

20 FEB 2021 00:01

Patient Cloud Close Date & Time

24 FEB 2021 23:59

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 FEB 2021 10:21:03

Patient Cloud Open Date & Time

27 FEB 2021 00:01

Patient Cloud Close Date & Time

03 MAR 2021 23:59

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

| TIMEPOINT | DAY 201 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 06 MAR 2021 03:03:31 |
| Patient Cloud Open Date & Time | 06 MAR 2021 00:01 |
| Patient Cloud Close Date & Time | 10 MAR 2021 23:59 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

16 MAR 2021 11:10:35

Patient Cloud Open Date & Time

13 MAR 2021 00:01

Patient Cloud Close Date & Time

17 MAR 2021 23:59

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

21 MAR 2021 09:04:50

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

29 MAR 2021 02:04:15

Patient Cloud Open Date & Time

27 MAR 2021 00:01

Patient Cloud Close Date & Time

31 MAR 2021 23:59

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

04 APR 2021 00:31:00

Patient Cloud Open Date & Time

03 APR 2021 00:01

Patient Cloud Close Date & Time

07 APR 2021 23:59

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

11 APR 2021 12:29:38

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

18 APR 2021 17:15:53

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

24 APR 2021 04:41:08

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

DAY 257

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

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

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

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

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

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

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

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

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

[Patient Cloud Close Date & Time](#)

05 MAY 2021 23:59

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

| TIMEPOINT | DAY 271 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="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"/> |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

DAY 278

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

DAY 285

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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 ☐

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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 ☐

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

| 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"/> |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

| TIMEPOINT | DAY 327 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

| TIMEPOINT | DAY 341 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

| TIMEPOINT | DAY 348 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

DAY 355

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

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

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

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

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

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

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

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

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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 ☐

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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 ☐

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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°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 ☐

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

DAY 390

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

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

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

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

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

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

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

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

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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 ☐

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

| 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"/> |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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 ☐

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

| TIMEPOINT | DAY 425 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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 ☐

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

| TIMEPOINT | DAY 439 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

| 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"/> |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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 ☐

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

| 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"/> |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

| TIMEPOINT | DAY 467 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature \geq 100.4°F/38°C) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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 ☐

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

| 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"/> |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

| TIMEPOINT | DAY 488 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="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"/> |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

| 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"/> |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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 ☐

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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 ☐

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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 ☐

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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 ☐

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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 ☐

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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 ☐

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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 ☐

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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 ☐

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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 ☐

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

DAY 586

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

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

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

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

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

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

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

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

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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 ☐

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

| 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"/> |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

| 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"/> |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

| 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"/> |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 APR 2022 23:59

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

| TIMEPOINT | DAY 621 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

| 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"/> |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

DAY 635

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

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

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

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

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

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

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

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

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

| 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"/> |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

DAY 656

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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 ☐

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2022 23:59

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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 ☐

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

DAY 684

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

| 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"/> |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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 ☐

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2022 23:59

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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 ☐

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

[Patient Cloud Close Date & Time](#)

27 JUL 2022 23:59

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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 ☐

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

| TIMEPOINT | DAY 719 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

DAY 726

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

Date and time of submission

| | |
|--|-------------------|
| Patient Cloud Open Date & Time | 13 AUG 2022 00:01 |
|--|-------------------|

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

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

| 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"/> |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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 ☐

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

| 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 <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"/> |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2022 23:59

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

| 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"/> |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

| TIMEPOINT | DAY 768 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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 ☐

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

DAY 782

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

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

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

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

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

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

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

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

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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 ☐

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

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

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

| TIMEPOINT | DAY 796 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

| | |
|---|-------------------|
| Patient Cloud Close Date & Time | 26 OCT 2022 23:59 |
|---|-------------------|

US3722338

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:26:23

| Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other? | Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache? | Date & Time of Submission |
|---|--|---------------------------|
| No | | 28 FEB 2021 10:20:41 |

US3722338

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 25 Feb 2021 17:47:46

Generated On: 10 Jun 2021 09:26:23

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

US3722338

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 25 Feb 2021 17:47:46

Generated On: 10 Jun 2021 09:26:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722338

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 21:56:15

Generated On: 10 Jun 2021 09:26:23

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

US3722338

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:56:15

Generated On: 10 Jun 2021 09:26:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722338

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 21:56:15

Generated On: 10 Jun 2021 09:26:23

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

US3722338

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:56:15

Generated On: 10 Jun 2021 09:26:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722338

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 21:56:15

Generated On: 10 Jun 2021 09:26:23

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 11 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3722338

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:56:15

Generated On: 10 Jun 2021 09:26:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722338

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 09 Mar 2021 11:33:22

Generated On: 10 Jun 2021 09:26:23

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 8 MAR 2021 |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/> |
| | Clinic <input checked="" type="radio"/> |
| Folder OID | VISIT4 |

US3722338

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 21:56:15

Generated On: 10 Jun 2021 09:26:23

| | |
|-------------------------------------|---------------------------------------|
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 8 MAR 2021 |
| Time of assessment (00:00-23:59) | 13:59 (24 HR) |
| Vital Signs Date and Time (derived) | 8 MAR 2021 13:59 |
| 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) | 80 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 17 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 120 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 66 mmHg |
| Diastolic Blood Pressure units | MMHG |
| Height (derived) | |
| Weight (derived) | |

US3722338

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Mar 2021 11:33:22

Generated On: 10 Jun 2021 09:26:23

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.

US3722338

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Mar 2021 11:33:22

Generated On: 10 Jun 2021 09:26:23

| | |
|------------------------------------|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (dd MMM yyyy) | 8 MAR 2021 |
| Collection time (00:00-23:59) | 14:32 (24 HR) |
| Collection date and time (derived) | 8 MAR 2021 14:32 |

US3722338

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 11:33:22

Generated On: 10 Jun 2021 09:26:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722338

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 21:56:15

Generated On: 10 Jun 2021 09:26:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3722338

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:56:15

Generated On: 10 Jun 2021 09:26:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722338

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:26:23

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

US3722338

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:26:23

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3722338

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:26:23

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

US3722338

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 09:26:23

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3722338

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

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 21:56:13

Generated On: 10 Jun 2021 09:26:23

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

| | |
|--------------------------|-------------|
| Visit date (dd MMM yyyy) | 11 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 |
|------------|---------------|

US3722338

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

Form: Unblinding

Data signed: (b) (4) 28 Apr 2021 21:56:13

Generated On: 10 Jun 2021 09:26:23

| | |
|---|---|
| Date of updated informed consent (<i>dd MMM yyyy</i>) | 11 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>) | 11 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 |

US3722338

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 28 Apr 2021 21:56:13

Generated On: 10 Jun 2021 09:26:23

| | |
|-------------|--|
| Height | |
| Weight | |
| BMI (xxx.x) | |

US3722338

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 28 Apr 2021 21:56:13

Generated On: 10 Jun 2021 09:26:23

| | |
|-------------------------------------|--|
| Height | |
| Weight | |
| BMI (xxx.x) | |
| Timepoint | Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/> |
| Were vital signs assessed? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 11 JAN 2021 |
| Time of assessment (00:00-23:59) | 13:40 (24 HR) |
| Vital Signs Date and Time (derived) | 11 JAN 2021 13:40 |
| Temperature (xxx.x) | 98 F |
| Route of measurement | Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 76 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 16 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 126 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 70 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3722338

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 28 Apr 2021 21:56:13

Generated On: 10 Jun 2021 09:26:23

| | |
|-------------------------------------|--|
| Height | |
| Weight | |
| BMI (xxx.x) | |
| Timepoint | Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/> |
| Were vital signs assessed? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 11 JAN 2021 |
| Time of assessment (00:00-23:59) | 14:14 (24 HR) |
| Vital Signs Date and Time (derived) | 11 JAN 2021 14:14 |
| 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) | 71 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 17 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 126 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 66 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3722338

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

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 21:56:13

Generated On: 10 Jun 2021 09:26:23

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 JAN 2021

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

US3722338

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

Form: Exposure

Data signed: (b) (4) 28 Apr 2021 21:56:13

Generated On: 10 Jun 2021 09:26:23

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) 11 JAN 2021

What was the treatment time? (00:00-23:59) 13:44 (24 HR)

Treatment Date and Time (derived) 11 JAN 2021 13:44

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

US3722338

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 21:56:13

Generated On: 10 Jun 2021 09:26:23

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

11 JAN 2021

Collection time (00:00-23:59)

13:20 (24 HR)

Collection date and time (derived)

11 JAN 2021 13:20

US3722338

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 28 Apr 2021 21:56:13

Generated On: 10 Jun 2021 09:26:23

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

| | |
|-------------------------------|-------------|
| Collection date (dd MMM yyyy) | 11 JAN 2021 |
|-------------------------------|-------------|

| | |
|---------------------------------|-------|
| Collection time (00:00 - 23:59) | 13:22 |
|---------------------------------|-------|

| | |
|------------------------------------|-------------------|
| Collection Date and Time (derived) | 11 JAN 2021 13:22 |
|------------------------------------|-------------------|

US3722338

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

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:56:13

Generated On: 10 Jun 2021 09:26:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722338

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 21:56:15

Generated On: 10 Jun 2021 09:26:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3722338

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:56:15

Generated On: 10 Jun 2021 09:26:23

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

US3722338

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 21:56:13

Generated On: 10 Jun 2021 09:26:23

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 8 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 |

US3722338

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 28 Apr 2021 21:56:13

Generated On: 10 Jun 2021 09:26:23

| | |
|-------------------------------------|---|
| 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) | 8 FEB 2021 |
| Time of assessment (00:00-23:59) | 15:36 (24 HR) |
| Vital Signs Date and Time (derived) | 8 FEB 2021 15:36 |
| Temperature (xxx.x) | 98 F |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 89 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 15 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 114 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 62 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3722338

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 28 Apr 2021 21:56:13

Generated On: 10 Jun 2021 09:26:23

| | |
|-------------------------------------|--|
| 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) | 8 FEB 2021 |
| Time of assessment (00:00-23:59) | 16:17 (24 HR) |
| Vital Signs Date and Time (derived) | 8 FEB 2021 16:17 |
| 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) | 92 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 17 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 121 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 64 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3722338

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 21:56:13

Generated On: 10 Jun 2021 09:26:23

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.

US3722338

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 28 Apr 2021 21:56:13

Generated On: 10 Jun 2021 09:26:23

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) 8 FEB 2021

What was the treatment time? (00:00-23:59) 15:47 (24 HR)

Treatment Date and Time (derived) 8 FEB 2021 15:47

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

US3722338

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:56:13

Generated On: 10 Jun 2021 09:26:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722338

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 21:56:15

Generated On: 10 Jun 2021 09:26:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3722338

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:56:15

Generated On: 10 Jun 2021 09:26:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722338

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 21:56:13

Generated On: 10 Jun 2021 09:26:23

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 8 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 |

US3722338

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 21:56:13

Generated On: 10 Jun 2021 09:26:23

| | |
|---|---------------------------------------|
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (<i>dd MMM yyyy</i>) | 8 MAR 2021 |
| Time of assessment (<i>00:00-23:59</i>) | 13:59 (24 HR) |
| Vital Signs Date and Time (derived) | 8 MAR 2021 13:59 |
| Temperature (<i>xxx.x</i>) | 97.8 F |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (<i>xxx</i>) | 80 beats/min |
| Pulse units | BPM |
| Respiratory Rate (<i>xxx</i>) | 17 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (<i>xxx</i>) | 120 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (<i>xxx</i>) | 66 mmHg |
| Diastolic Blood Pressure units | MMHG |
| Height (derived) | |
| Weight (derived) | |

US3722338

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 21:56:13

Generated On: 10 Jun 2021 09:26:23

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.

US3722338

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 21:56:13

Generated On: 10 Jun 2021 09:26:23

| | |
|------------------------------------|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (dd MMM yyyy) | 8 MAR 2021 |
| Collection time (00:00-23:59) | 14:32 (24 HR) |
| Collection date and time (derived) | 8 MAR 2021 14:32 |

US3722338

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 28 Apr 2021 21:56:11

Generated On: 10 Jun 2021 09:26:23

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3722338

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:26:23

AEID

Adverse event

LEFT ARM INJECTION SITE

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)

19 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

23 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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US3722338

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:26:23

| | |
|--|---|
| 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 type="radio"/> Related <input checked="" 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 checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/> |
| Other action taken (check all that apply) | |
| None | False |
| Concomitant Medication | True |
| Concomitant Procedure | False |
| Outcome | Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/> |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: | |
| Narrative | |
| Serious Adverse Event Derived (CSA Programming Field Only) | 0 |
| Medically Attended AE Derived (CSA Programming Field Only) | 0 |
| Admitted to ICU Derived (CSA Programming Field Only) | |

US3722338

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:26:23

AEID

Adverse event

INJECTION SITE LEFT ARM
SWELLING

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) 19 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing? Yes ☐
No ☒

If not Ongoing, end date (dd MMM yyyy) 23 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity Grade 1/Mild ☐
Grade 2/Moderate ☒
Grade 3/Severe ☐
Grade 4 ☐

Is the adverse event serious? Yes ☐
No ☒

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU? Yes ☐
No ☐
Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:26:23

| | |
|--|---|
| 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 type="radio"/> Related <input checked="" 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 checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/> |
| Other action taken (check all that apply) | |
| None | False |
| Concomitant Medication | True |
| Concomitant Procedure | False |
| Outcome | Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/> |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: | |
| Narrative | |
| Serious Adverse Event Derived (CSA Programming Field Only) | 0 |
| Medically Attended AE Derived (CSA Programming Field Only) | 0 |
| Admitted to ICU Derived (CSA Programming Field Only) | |

US3722338

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:26:23

| | |
|--|--|
| AEID | USA-US083-2020-MRNA-1273-P30 1000002 |
| Adverse event | ACUTE INCARCERATED LEFT HERNIA LOWER QUADRANT |
| Was this a medically-attended AE? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Was this a Solicited Adverse Reaction? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Is this event a confirmed diagnosis of Symptomatic Covid-19? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Start date (dd MMM yyyy) | 12 OCT 2020 |
| Start time (00:00-23:59) | |
| AE start date and time (derived) | |
| Ongoing? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| If not Ongoing, end date (dd MMM yyyy) | 21 OCT 2020 |
| End time (00:00-23:59) | |
| AE End Date and Time (derived) | |
| Severity | Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/> |
| Is the adverse event serious? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| AE is serious due To (check all that apply) | |
| Death | False |
| Life threatening | False |
| Requires inpatient or prolongation of existing Hospitalization | True |
| Hospital Admission Date (dd MMM yyyy) | 12 OCT 2020 |
| Hospital Discharge Date (dd MMM yyyy) | 21 OCT 2020 |
| Admitted to ICU? | Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/> |
| Number of Days in ICU | |
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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:26:23

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

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:26:23

SUBJECT CONTACTED SITE
AND STATED THAT HE WAS
ADMITTED TO THE HOSPITAL
AROUND 12OCT2020 FOR
HERNIA REPAIR. SITE TO
REPORT SAE TODAY AND WILL
OBTAIN MEDICAL RECORD
RELEASE TO OBTAIN MEDICAL
RECORDS.

AFTER MANY UNSUCCESSFUL
ATTEMPTS BY SITE TO GET
SUBJECT IN FOR MEDICAL
RECORDS RELEASE, THE
SUBJECT CAME IN FOR THE
UNBLINDING VISIT AND A
RELEASE WAS OBTAINED.
MEDICAL RECORDS WERE
RECEIVED FOR FOLLOW UP.
SUBJECT HAD LONGSTANDING
HERNIA THAT WAS REPAIRED
WITH MESH ON 12 OCT 2020.

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

US3722338

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:26:23

| | |
|--|--|
| AEID | USA-US083-2021-MRNA-1273-P30 1000003 |
| Adverse event | URINARY TRACT INFECTION |
| 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) | 26 OCT 2020 |
| Start time (00:00-23:59) | |
| AE start date and time (derived) | |
| Ongoing? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| If not Ongoing, end date (dd MMM yyyy) | 10 NOV 2020 |
| End time (00:00-23:59) | |
| AE End Date and Time (derived) | |
| Severity | Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/> |
| Is the adverse event serious? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| AE is serious due To (check all that apply) | |
| Death | False |
| Life threatening | False |
| Requires inpatient or prolongation of existing Hospitalization | True |
| Hospital Admission Date (dd MMM yyyy) | 26 OCT 2020 |
| Hospital Discharge Date (dd MMM yyyy) | 28 OCT 2020 |
| Admitted to ICU? | Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/> |
| Number of Days in ICU | |

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:26:23

| | |
|--|---|
| Persistent or significant disability or incapacity | False |
| Congenital anomaly or birth defect | False |
| Other medically important event | False |
| Relationship to investigational product | Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/> |
| Relationship to Study Procedure | Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/> |
| Action taken with investigational product | None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/> |
| Other action taken (check all that apply) | |
| None | False |
| Concomitant Medication | True |
| Concomitant Procedure | True |
| Outcome | Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/> |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: | |
| Narrative | AFTER FOLEY CATHETER WAS PLACED FOR ACUTE URINARY RETENTION, SUBJECT DID NOT PROVIDE PROPER CARE FOR THE CATHETER, LEADING TO A UTI THAT REQUIRED HOSPITALIZATION AND REPLACEMENT OF CATHETER. |
| Serious Adverse Event Derived (CSA Programming Field Only) | 1 |

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:26:23

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

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:26:23

| | |
|--|--|
| AEID | USA-US083-2021-MRNA-1273-P30 1000003 |
| Adverse event | PULMONARY EMBOLISM |
| 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) | 26 OCT 2020 |
| Start time (00:00-23:59) | |
| AE start date and time (derived) | |
| Ongoing? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| If not Ongoing, end date (dd MMM yyyy) | 28 OCT 2020 |
| End time (00:00-23:59) | |
| AE End Date and Time (derived) | |
| Severity | Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/> |
| Is the adverse event serious? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| AE is serious due To (check all that apply) | |
| Death | False |
| Life threatening | False |
| Requires inpatient or prolongation of existing Hospitalization | True |
| Hospital Admission Date (dd MMM yyyy) | 26 OCT 2020 |
| Hospital Discharge Date (dd MMM yyyy) | 28 OCT 2020 |
| Admitted to ICU? | Yes <input checked="" type="radio"/> No <input type="radio"/> Unknown <input type="radio"/> |
| Number of Days in ICU | 2 |

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:26:23

| | |
|--|---|
| 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 | AFTER INITIAL HOSPITALIZATION FOR HERNIA REPAIR, SUBJECT DID NOT TAKE MEDICATIONS AS PRESCRIBED, RESULTING IN A PULMONARY EMBOLISM. SUBJECT HOSPITALIZED AND DISCHARGED ON 28 OCT 2020. |
| Serious Adverse Event Derived (CSA Programming Field Only) | 1 |

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:26:23

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

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:26:23

| | |
|--|--|
| AEID | USA-US083-2020-MRNA-1273-P30 1000002 |
| Adverse event | ACUTE URINARY RETENTION |
| Was this a medically-attended AE? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Was this a Solicited Adverse Reaction? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Is this event a confirmed diagnosis of Symptomatic Covid-19? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Start date (dd MMM yyyy) | 14 OCT 2020 |
| Start time (00:00-23:59) | |
| AE start date and time (derived) | |
| Ongoing? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| If not Ongoing, end date (dd MMM yyyy) | 26 OCT 2020 |
| End time (00:00-23:59) | |
| AE End Date and Time (derived) | |
| Severity | Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/> |
| Is the adverse event serious? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| AE is serious due To (check all that apply) | |
| Death | False |
| Life threatening | False |
| Requires inpatient or prolongation of existing Hospitalization | True |
| Hospital Admission Date (dd MMM yyyy) | 12 OCT 2020 |
| Hospital Discharge Date (dd MMM yyyy) | 21 OCT 2020 |
| Admitted to ICU? | Yes <input checked="" type="radio"/> No <input type="radio"/> Unknown <input type="radio"/> |
| Number of Days in ICU | 2 |

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:26:23

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

US3722338

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:26:23

SUBJECT HOSPITALIZED FOR
HERNIA REPAIR. FOLLOWING
REPAIR, SUBJECT HAD ACUTE
URINARY RETENTION
PROLONGING THE STAY.
COUDE FOLEY CATHETER WAS
PLACED.

10-26

RBC 3.09 4.5-5.9 MIL/MM3
HEMOGLOBIN 9.1 12.5-17.5 G/DL
HEATOCRIT 27.9 41-53%
RDW 16.2 12-16%
NETROPHILS 8.1 1.4 – 6.6
TH/MM3
LYMPOCYTES .8 1- 3.5 TH/MM3

10-20

HGB 7.7
HCT 23.6

10-21

HGB 7.8
HCT 24.6

| | |
|--|---|
| 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) | 1 |

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:26:23

| | |
|--|---|
| AEID | |
| Adverse event | SUBCLAVIAN LEFT SIDED DVT |
| 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) | 2 OCT 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 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 | |
| Persistent or significant disability or incapacity | False |

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:26:23

| | |
|--|---|
| Congenital anomaly or birth defect | False |
| Other medically important event | False |
| Relationship to investigational product | Not Related <input type="radio"/> Related <input type="radio"/> Not Applicable <input checked="" type="radio"/> |
| Relationship to Study Procedure | Not Related <input type="radio"/> Related <input type="radio"/> Not Applicable <input checked="" type="radio"/> |
| Action taken with investigational product | None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input 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 type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" type="radio"/> Unknown <input type="radio"/> |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: | |
| Narrative | |
| Serious Adverse Event Derived (CSA Programming Field Only) | 0 |
| Medically Attended AE Derived (CSA Programming Field Only) | 1 |
| Admitted to ICU Derived (CSA Programming Field Only) | |

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:26:23

AEID

Adverse event

HYPOXIA

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)

26 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐
No ☒

If not Ongoing, end date (dd MMM yyyy)

28 OCT 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

Persistent or significant disability or incapacity

False

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Folder: Adverse Events

Form: Adverse Events (8)

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| | |
|---|---|
| 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 checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input 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) | _____ |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 28 Apr 2021 21:56:13

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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) 28 Apr 2021 21:56:11

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Name of Medication HUMOLOG

Prophylaxis Yes ☐
No ☒

Indication DIABETES 2

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 (1)

Data signed: (b) (4) 28 Apr 2021 21:56:11

Generated On: 10 Jun 2021 09:26:23

| | | |
|--|--------------------------|----------------------------------|
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | UN | UNK 1994 |
| 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) | 4 | |
| 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 (2)

Data signed: (b) (4) 28 Apr 2021 21:56:11

Generated On: 10 Jun 2021 09:26:23

Name of Medication LANTUS

Prophylaxis Yes ☐
No ☒

Indication DIABETES 2

Dose per administration 70

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 21:56:11

Generated On: 10 Jun 2021 09:26:23

| | | |
|--|--------------------------|----------------------------------|
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | UN UNK 1993 | |
| 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) 28 Apr 2021 21:56:11

Generated On: 10 Jun 2021 09:26:23

Name of Medication SYNJARDY

Prophylaxis Yes ☐
No ☒

Indication DIABETES 2

Dose per administration 5/1000

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 21:56:11

Generated On: 10 Jun 2021 09:26:23

| | | |
|--|--------------------------|----------------------------------|
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | UN UNK 2018 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | 2 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 28 Apr 2021 21:56:11

Generated On: 10 Jun 2021 09:26:23

Name of Medication LISINOPRIL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

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 (4)

Data signed: (b) (4) 28 Apr 2021 21:56:11

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| | | |
|--|--------------------------|----------------------------------|
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | UN UNK 2017 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | 2 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 28 Apr 2021 21:56:11

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Name of Medication PRAVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 28 Apr 2021 21:56:11

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| | | |
|--|--------------------------|----------------------------------|
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | UN UNK 2017 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | 1 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 28 Apr 2021 21:56:11

Generated On: 10 Jun 2021 09:26:23

Name of Medication ASPIRIN

Prophylaxis Yes ☐
No ☒

Indication LEFT ARM PAIN AND SWELLING

Dose per administration 325

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 28 Apr 2021 21:56:11

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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) | | 19 SEP 2020 |
| Start date completely unknown | | False |
| Ongoing? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) | | 23 SEP 2020 |
| Was this medication taken for solicited event? | Yes | <input checked="" type="checkbox"/> |
| | No | <input type="checkbox"/> |
| Separate Dosage Number (derived) _____ | | |
| Interval Dosage Unit Number (derived) _____ | | |
| Interval Dosage Definition (derived) | 802 | <input type="checkbox"/> |
| | 803 | <input type="checkbox"/> |
| | 804 | <input type="checkbox"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 28 Apr 2021 21:56:11

Generated On: 10 Jun 2021 09:26:23

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication LEFT ARM PAIN AND
SWELLING

Dose per administration 200

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 (7)

Data signed: (b) (4) 28 Apr 2021 21:56:11

Generated On: 10 Jun 2021 09:26:23

| | | |
|--|--------------------------|-------------------------------------|
| | 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) | | 19 SEP 2020 |
| Start date completely unknown | | False |
| Ongoing? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) | | 23 SEP 2020 |
| Was this medication taken for solicited event? | Yes | <input checked="" type="checkbox"/> |
| | No | <input 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 (8)

Data signed: (b) (4) 28 Apr 2021 21:56:11

Generated On: 10 Jun 2021 09:26:23

Name of Medication XARELTO

Prophylaxis Yes ☐
No ☒

Indication LEFT SIDED DVT

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 (8)

Data signed: (b) (4) 28 Apr 2021 21:56:11

Generated On: 10 Jun 2021 09:26:23

| | | |
|--|--------------------------|----------------------------------|
| | 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) | | 02 OCT 2020 |
| Start date completely unknown | | False |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | | 1 |
| Interval Dosage Unit Number (derived) | | 1 |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 28 Apr 2021 21:56:11

Generated On: 10 Jun 2021 09:26:23

Name of Medication DILAUDID

Prophylaxis Yes ☐
No ☒

Indication PAIN RELATED TO ACUTE
INCARCERATED LEFT HERNIA
REPAIR WITH MESH

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 28 Apr 2021 21:56:11

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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) | 28 OCT 2020 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) | 03 NOV 2020 | |
| Was this medication taken for solicited event? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived) | | |
| Interval Dosage Unit Number (derived) | | |
| Interval Dosage Definition (derived) | 802 | <input type="checkbox"/> |
| | 803 | <input type="checkbox"/> |
| | 804 | <input type="checkbox"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 28 Apr 2021 21:56:11

Generated On: 10 Jun 2021 09:26:23

Name of Medication FENTANYL

Prophylaxis Yes ☐
No ☒

Indication PAIN RELATED TO ACUTE
INCARCERATED LEFT HERNIA
REPAIR WITH MESH

Dose per administration

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 (10)

Data signed: (b) (4) 28 Apr 2021 21:56:11

Generated On: 10 Jun 2021 09:26:23

| | | |
|--|--------------------------|-------------------------------------|
| | 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 OCT 2020 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) | | 21 OCT 2020 |
| Was this medication taken for solicited event? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived) | | |
| Interval Dosage Unit Number (derived) | | |
| Interval Dosage Definition (derived) | 802 | <input type="checkbox"/> |
| | 803 | <input type="checkbox"/> |
| | 804 | <input type="checkbox"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 28 Apr 2021 21:56:11

Generated On: 10 Jun 2021 09:26:23

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication PAIN RELATED TO ACUTE
INCARCERATED LEFT HERNIA
REPAIR WITH MESH

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 28 Apr 2021 21:56:11

Generated On: 10 Jun 2021 09:26:23

| | | |
|--|--------------------------|-------------------------------------|
| | 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) | 14 OCT 2020 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) | 31 OCT 2020 | |
| Was this medication taken for solicited event? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived) | | |
| Interval Dosage Unit Number (derived) | | |
| Interval Dosage Definition (derived) | 802 | <input type="checkbox"/> |
| | 803 | <input type="checkbox"/> |
| | 804 | <input type="checkbox"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 28 Apr 2021 21:56:11

Generated On: 10 Jun 2021 09:26:23

Name of Medication TRAMADOL

Prophylaxis Yes ☐
No ☒

Indication PAIN RELATED TO ACUTE
INCARCERATED LEFT HERNIA
REPAIR WITH MESH

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 ☐

PRODUCTION RELEASE (v12.003
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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 28 Apr 2021 21:56:11

Generated On: 10 Jun 2021 09:26:23

| | | |
|--|--------------------------|-------------------------------------|
| | 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) | 21 OCT 2020 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) | | 28 OCT 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 (13)

Data signed: (b) (4) 28 Apr 2021 21:56:11

Generated On: 10 Jun 2021 09:26:23

Name of Medication LOVENOX

Prophylaxis Yes ☐
No ☒

Indication LEFT HERNIA REPAIR WITH
MESH

Dose per administration

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 (13)

Data signed: (b) (4) 28 Apr 2021 21:56:11

Generated On: 10 Jun 2021 09:26:23

| | | |
|--|--------------------------|-------------------------------------|
| | 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) | 21 OCT 2020 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) | | 28 OCT 2020 |
| Was this medication taken for solicited event? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived) _____ | | |
| Interval Dosage Unit Number (derived) _____ | | |
| Interval Dosage Definition (derived) | 802 | <input type="checkbox"/> |
| | 803 | <input type="checkbox"/> |
| | 804 | <input type="checkbox"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 28 Apr 2021 21:56:11

Generated On: 10 Jun 2021 09:26:23

Name of Medication ROCEPHIN

Prophylaxis Yes ☐
No ☒

Indication URINARY TRACT INFECTION

Dose per administration

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 (14)

Data signed: (b) (4) 28 Apr 2021 21:56:11

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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) | 26 OCT 2020 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) | | 28 OCT 2020 |
| Was this medication taken for solicited event? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived) _____ | | |
| Interval Dosage Unit Number (derived) _____ | | |
| Interval Dosage Definition (derived) | 802 | <input type="checkbox"/> |
| | 803 | <input type="checkbox"/> |
| | 804 | <input type="checkbox"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 28 Apr 2021 21:56:11

Generated On: 10 Jun 2021 09:26:23

Name of Medication ZOFRAN

Prophylaxis Yes ☐
No ☒

Indication URINARY TRACT INFECTION

Dose per administration

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 28 Apr 2021 21:56:11

Generated On: 10 Jun 2021 09:26:23

| | | |
|--|--------------------------|-------------------------------------|
| | 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) | 26 OCT 2020 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) | 28 OCT 2020 | |
| Was this medication taken for solicited event? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived) | _____ | |
| Interval Dosage Unit Number (derived) | _____ | |
| Interval Dosage Definition (derived) | 802 | <input type="checkbox"/> |
| | 803 | <input type="checkbox"/> |
| | 804 | <input type="checkbox"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 28 Apr 2021 21:56:11

Generated On: 10 Jun 2021 09:26:23

Name of Medication NOVOLOG FLEXPEN

Prophylaxis Yes ☐
No ☒

Indication DIABETES 2

Dose per administration 100

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

If dose unit is Other, specify UNIT/ML

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)

Data signed: (b) (4) 28 Apr 2021 21:56:11

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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 MAR 2016 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | 3 | |
| 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 (17)

Data signed: (b) (4) 28 Apr 2021 21:56:11

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Name of Medication VENTOLIN HFA

Prophylaxis Yes ☐
No ☒

Indication SHORTNESS OF BREATH

Dose per administration 90

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)

Data signed: (b) (4) 28 Apr 2021 21:56:11

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| | | |
|--|--------------------------|-------------------------------------|
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input checked="" 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 MAR 2016 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="checkbox"/> |
| | No | <input type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| 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 (18)

Data signed: (b) (4) 28 Apr 2021 21:56:11

Generated On: 10 Jun 2021 09:26:23

Name of Medication FLUTICASONE

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

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 (18)

Data signed: (b) (4) 28 Apr 2021 21:56:11

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| | | |
|--|--------------------------|-------------------------------------|
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input checked="" 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) | 28 OCT 2016 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="checkbox"/> |
| | No | <input type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived) | 1 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="checkbox"/> |
| | 803 | <input type="checkbox"/> |
| | 804 | <input checked="" type="checkbox"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 28 Apr 2021 21:56:11

Generated On: 10 Jun 2021 09:26:23

Name of Medication VITAMIN D3

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration 10000

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) 28 Apr 2021 21:56:11

Generated On: 10 Jun 2021 09:26:23

| | | |
|--|--------------------------|----------------------------------|
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | 13 OCT 2020 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | 1 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 28 Apr 2021 21:56:11

Generated On: 10 Jun 2021 09:26:23

Name of Medication ZINC

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

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 ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 28 Apr 2021 21:56:11

Generated On: 10 Jun 2021 09:26:23

| | | |
|--|--------------------------|----------------------------------|
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | 13 OCT 2020 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | 1 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 28 Apr 2021 21:56:11

Generated On: 10 Jun 2021 09:26:23

Name of Medication PROSCAR

Prophylaxis Yes ☐
No ☒

Indication ACUTE URINARY RETENTION
REQUIRING FOLEY CATHETER

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 28 Apr 2021 21:56:11

Generated On: 10 Jun 2021 09:26:23

| | | |
|--|--------------------------|-------------------------------------|
| | 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) | 21 OCT 2020 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) | | 21 OCT 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"/> |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 28 Apr 2021 21:56:11

Generated On: 10 Jun 2021 09:26:23

Name of Medication OXYGEN

Prophylaxis Yes ☐
No ☒

Indication ACUTE HYPOXEMIC
RESPIRATORY FAILURE

Dose per administration UNK

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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US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 28 Apr 2021 21:56:11

Generated On: 10 Jun 2021 09:26:23

| | | |
|--|--------------------------|----------------------------------|
| | Intraocular | <input type="radio"/> |
| | Intramuscular | <input type="radio"/> |
| | Respiratory (Inhalation) | <input checked="" 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) | 26 OCT 2020 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) | 28 OCT 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"/> |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 28 Apr 2021 21:56:11

Generated On: 10 Jun 2021 09:26:23

Name of Medication KLONOPIN

Prophylaxis Yes ☐
No ☒

Indication ANXIETY

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 ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 28 Apr 2021 21:56:11

Generated On: 10 Jun 2021 09:26:23

| | | |
|--|--------------------------|----------------------------------|
| | 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) | 17 MAR 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"/> |

US3722338

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 28 Apr 2021 21:56:13

Generated On: 10 Jun 2021 09:26:23

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3722338

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 28 Apr 2021 21:56:13

Generated On: 10 Jun 2021 09:26:23

| Procedure/Surgery date (dd MMM yyyy) | Procedure/Surgery | Indication | If indication is Other, specify |
|---|-------------------------------------|---------------|---------------------------------|
| 12 OCT 2020 | HERNIA REPAIR | Adverse Event | |
| 14 OCT 2020 | COUDE FOLEY CATHETER PLACEMENT | Adverse Event | |
| 26 OCT 2020 | COUDE FOLEY CATHETER REPLACEMENT | Adverse Event | |

US3722338

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:26:23

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

US3722338

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:26:23

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 ☐

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Data signed: (b) (4) 28 Apr 2021 21:56:13

Generated On: 10 Jun 2021 09:26:23

| | |
|--|--|
| SAEID | USA-US083-2020-MRNA-1273-P301000002 |
| 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 | LUIS |
| Investigator's Last Name | DE LA CRUZ |
| Site Address: Street | 2 ROPER CORNERS CIR |
| Site Address: City | GREENVILLE |
| Site Address: State | SC |
| Site Address: Postal Code | 29615 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 14 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Data signed: (b) (4) 28 Apr 2021 21:56:13

Generated On: 10 Jun 2021 09:26:23

| | |
|---|--|
| SAEID | USA-US083-2020-MRNA-1273-P301000002 |
| 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 | LUIS |
| Investigator's Last Name | DE LA CRUZ |
| Site Address: Street | 2 ROPER CORNERS CIR |
| Site Address: City | GREENVILLE |
| Site Address: State | SC |
| Site Address: Postal Code | 29615 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 14 |
| Date of submission (Pre-filled from custom function) | 23/OCT/2020 19:53 |
| 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 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Data signed: (b) (4) 28 Apr 2021 21:56:13

Generated On: 10 Jun 2021 09:26:23

| | |
|---|--|
| SAEID | USA-US083-2020-MRNA-1273-P301000002 |
| 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 | LUIS |
| Investigator's Last Name | DE LA CRUZ |
| Site Address: Street | 2 ROPER CORNERS CIR |
| Site Address: City | GREENVILLE |
| Site Address: State | SC |
| Site Address: Postal Code | 29615 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 14 |
| Date of submission (Pre-filled from custom function) | 04/NOV/2020 10:01 |
| 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 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Data signed: (b) (4) 28 Apr 2021 21:56:13

Generated On: 10 Jun 2021 09:26:23

| | |
|---|--|
| SAEID | USA-US083-2020-MRNA-1273-P301000002 |
| 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 | LUIS |
| Investigator's Last Name | DE LA CRUZ |
| Site Address: Street | 2 ROPER CORNERS CIR |
| Site Address: City | GREENVILLE |
| Site Address: State | SC |
| Site Address: Postal Code | 29615 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 14 |
| Date of submission (Pre-filled from custom function) | 25/NOV/2020 14:12 |
| 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 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Data signed: (b) (4) 28 Apr 2021 21:56:13

Generated On: 10 Jun 2021 09:26:23

| | |
|---|--|
| SAEID | USA-US083-2020-MRNA-1273-P301000002 |
| 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 | LUIS |
| Investigator's Last Name | DE LA CRUZ |
| Site Address: Street | 2 ROPER CORNERS CIR |
| Site Address: City | GREENVILLE |
| Site Address: State | SC |
| Site Address: Postal Code | 29615 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 14 |
| Date of submission (Pre-filled from custom function) | 13/JAN/2021 17:04 |
| Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge. | True |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form (5)

Data signed: (b) (4) 28 Apr 2021 21:56:13

Generated On: 10 Jun 2021 09:26:23

| | |
|---|--|
| SAEID | USA-US083-2020-MRNA-1273-P301000002 |
| 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 | LUIS |
| Investigator's Last Name | DE LA CRUZ |
| Site Address: Street | 2 ROPER CORNERS CIR |
| Site Address: City | GREENVILLE |
| Site Address: State | SC |
| Site Address: Postal Code | 29615 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 14 |
| Date of submission (Pre-filled from custom function) | 20/JAN/2021 15:45 |
| 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 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form (6)

Data signed: (b) (4) 28 Apr 2021 21:56:13

Generated On: 10 Jun 2021 09:26:23

| | |
|---|--|
| SAEID | USA-US083-2020-MRNA-1273-P301000002 |
| 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 | LUIS |
| Investigator's Last Name | DE LA CRUZ |
| Site Address: Street | 2 ROPER CORNERS CIR |
| Site Address: City | GREENVILLE |
| Site Address: State | SC |
| Site Address: Postal Code | 29615 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 14 |
| Date of submission (Pre-filled from custom function) | 18/FEB/2021 15:53 |
| 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 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form (7)

Data signed: (b) (4) 28 Apr 2021 21:56:13

Generated On: 10 Jun 2021 09:26:23

| | |
|---|--|
| SAEID | USA-US083-2020-MRNA-1273-P301000002 |
| 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 | LUIS |
| Investigator's Last Name | DE LA CRUZ |
| Site Address: Street | 2 ROPER CORNERS CIR |
| Site Address: City | GREENVILLE |
| Site Address: State | SC |
| Site Address: Postal Code | 29615 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 14 |
| Date of submission (Pre-filled from custom function) | 09/MAR/2021 10:26 |
| 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 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form (8)

Data signed: (b) (4) 28 Apr 2021 21:56:13

Generated On: 10 Jun 2021 09:26:23

| | |
|---|--|
| SAEID | USA-US083-2020-MRNA-1273-P301000002 |
| 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 | LUIS |
| Investigator's Last Name | DE LA CRUZ |
| Site Address: Street | 2 ROPER CORNERS CIR |
| Site Address: City | GREENVILLE |
| Site Address: State | SC |
| Site Address: Postal Code | 29615 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 14 |
| Date of submission (Pre-filled from custom function) | 10/MAR/2021 08:09 |
| 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 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form (9)

Data signed: (b) (4) 28 Apr 2021 21:56:13

Generated On: 10 Jun 2021 09:26:23

| | |
|---|--|
| SAEID | USA-US083-2020-MRNA-1273-P301000002 |
| 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 | LUIS |
| Investigator's Last Name | DE LA CRUZ |
| Site Address: Street | 2 ROPER CORNERS CIR |
| Site Address: City | GREENVILLE |
| Site Address: State | SC |
| Site Address: Postal Code | 29615 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 14 |
| Date of submission (Pre-filled from custom function) | 10/MAR/2021 08:31 |
| Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge. | True |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form (10)

Data signed: (b) (4) 28 Apr 2021 21:56:13

Generated On: 10 Jun 2021 09:26:23

| | |
|---|--|
| SAEID | USA-US083-2020-MRNA-1273-P301000002 |
| 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 | LUIS |
| Investigator's Last Name | DE LA CRUZ |
| Site Address: Street | 2 ROPER CORNERS CIR |
| Site Address: City | GREENVILLE |
| Site Address: State | SC |
| Site Address: Postal Code | 29615 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 14 |
| Date of submission (Pre-filled from custom function) | 02/APR/2021 12:46 |
| 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 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form (11)

Data signed: (b) (4) 28 Apr 2021 21:56:13

Generated On: 10 Jun 2021 09:26:23

| | |
|---|--|
| SAEID | USA-US083-2020-MRNA-1273-P301000002 |
| 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 | LUIS |
| Investigator's Last Name | DE LA CRUZ |
| Site Address: Street | 2 ROPER CORNERS CIR |
| Site Address: City | GREENVILLE |
| Site Address: State | SC |
| Site Address: Postal Code | 29615 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 14 |
| Date of submission (Pre-filled from custom function) | 08/APR/2021 08:35 |
| 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 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form (12)

Data signed: (b) (4) 28 Apr 2021 21:56:13

Generated On: 10 Jun 2021 09:26:23

| | |
|---|--|
| SAEID | USA-US083-2020-MRNA-1273-P301000002 |
| 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 | LUIS |
| Investigator's Last Name | DE LA CRUZ |
| Site Address: Street | 2 ROPER CORNERS CIR |
| Site Address: City | GREENVILLE |
| Site Address: State | SC |
| Site Address: Postal Code | 29615 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 14 |
| Date of submission (Pre-filled from custom function) | 16/APR/2021 14:10 |
| 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 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form (13)

Data signed: (b) (4) 28 Apr 2021 21:56:13

Generated On: 10 Jun 2021 09:26:23

| | |
|---|--|
| SAEID | USA-US083-2020-MRNA-1273-P301000002 |
| 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 | LUIS |
| Investigator's Last Name | DE LA CRUZ |
| Site Address: Street | 2 ROPER CORNERS CIR |
| Site Address: City | GREENVILLE |
| Site Address: State | SC |
| Site Address: Postal Code | 29615 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 14 |
| Date of submission (Pre-filled from custom function) | 19/APR/2021 13:22 |
| Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge. | True |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form (14)

Data signed: (b) (4) 28 Apr 2021 21:56:13

Generated On: 10 Jun 2021 09:26:23

| | |
|---|--|
| SAEID | USA-US083-2020-MRNA-1273-P301000002 |
| 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 | LUIS |
| Investigator's Last Name | DE LA CRUZ |
| Site Address: Street | 2 ROPER CORNERS CIR |
| Site Address: City | GREENVILLE |
| Site Address: State | SC |
| Site Address: Postal Code | 29615 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 14 |
| Date of submission (Pre-filled from custom function) | 28/APR/2021 07:57 |
| 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 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Data signed: (b) (4) 28 Apr 2021 21:56:14

Generated On: 10 Jun 2021 09:26:23

| | |
|--|--|
| SAEID | USA-US083-2021-MRNA-1273-P301000003 |
| 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 | LUIS |
| Investigator's Last Name | DE LA CRUZ |
| Site Address: Street | 2 ROPER CORNERS CIR |
| Site Address: City | GREENVILLE |
| Site Address: State | SC |
| Site Address: Postal Code | 29615 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 7 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form (1)

Data signed: (b) (4) 28 Apr 2021 21:56:14

Generated On: 10 Jun 2021 09:26:23

| | |
|---|--|
| SAEID | USA-US083-2021-MRNA-1273-P301000003 |
| 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 | LUIS |
| Investigator's Last Name | DE LA CRUZ |
| Site Address: Street | 2 ROPER CORNERS CIR |
| Site Address: City | GREENVILLE |
| Site Address: State | SC |
| Site Address: Postal Code | 29615 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 7 |
| Date of submission (Pre-filled from custom function) | 20/JAN/2021 17:02 |
| 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 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form (2)

Data signed: (b) (4) 28 Apr 2021 21:56:14

Generated On: 10 Jun 2021 09:26:23

| | |
|---|--|
| SAEID | USA-US083-2021-MRNA-1273-P301000003 |
| 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 | LUIS |
| Investigator's Last Name | DE LA CRUZ |
| Site Address: Street | 2 ROPER CORNERS CIR |
| Site Address: City | GREENVILLE |
| Site Address: State | SC |
| Site Address: Postal Code | 29615 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 7 |
| Date of submission (Pre-filled from custom function) | 18/FEB/2021 16:26 |
| 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 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form (3)

Data signed: (b) (4) 28 Apr 2021 21:56:14

Generated On: 10 Jun 2021 09:26:23

| | |
|---|--|
| SAEID | USA-US083-2021-MRNA-1273-P301000003 |
| 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 | LUIS |
| Investigator's Last Name | DE LA CRUZ |
| Site Address: Street | 2 ROPER CORNERS CIR |
| Site Address: City | GREENVILLE |
| Site Address: State | SC |
| Site Address: Postal Code | 29615 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 7 |
| Date of submission (Pre-filled from custom function) | 09/MAR/2021 10:45 |
| 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 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form (4)

Data signed: (b) (4) 28 Apr 2021 21:56:14

Generated On: 10 Jun 2021 09:26:23

| | |
|---|--|
| SAEID | USA-US083-2021-MRNA-1273-P301000003 |
| 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 | LUIS |
| Investigator's Last Name | DE LA CRUZ |
| Site Address: Street | 2 ROPER CORNERS CIR |
| Site Address: City | GREENVILLE |
| Site Address: State | SC |
| Site Address: Postal Code | 29615 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 7 |
| Date of submission (Pre-filled from custom function) | 10/MAR/2021 09:51 |
| Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge. | True |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form (5)

Data signed: (b) (4) 28 Apr 2021 21:56:14

Generated On: 10 Jun 2021 09:26:23

| | |
|---|--|
| SAEID | USA-US083-2021-MRNA-1273-P301000003 |
| 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 | LUIS |
| Investigator's Last Name | DE LA CRUZ |
| Site Address: Street | 2 ROPER CORNERS CIR |
| Site Address: City | GREENVILLE |
| Site Address: State | SC |
| Site Address: Postal Code | 29615 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 7 |
| Date of submission (Pre-filled from custom function) | 08/APR/2021 08:35 |
| 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 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form (6)

Data signed: (b) (4) 28 Apr 2021 21:56:14

Generated On: 10 Jun 2021 09:26:23

| | |
|---|--|
| SAEID | USA-US083-2021-MRNA-1273-P301000003 |
| 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 | LUIS |
| Investigator's Last Name | DE LA CRUZ |
| Site Address: Street | 2 ROPER CORNERS CIR |
| Site Address: City | GREENVILLE |
| Site Address: State | SC |
| Site Address: Postal Code | 29615 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 7 |
| Date of submission (Pre-filled from custom function) | 16/APR/2021 09:46 |
| 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 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form (7)

Data signed: (b) (4) 28 Apr 2021 21:56:14

Generated On: 10 Jun 2021 09:26:23

| | |
|---|--|
| SAEID | USA-US083-2021-MRNA-1273-P301000003 |
| 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 | LUIS |
| Investigator's Last Name | DE LA CRUZ |
| Site Address: Street | 2 ROPER CORNERS CIR |
| Site Address: City | GREENVILLE |
| Site Address: State | SC |
| Site Address: Postal Code | 29615 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 7 |
| Date of submission (Pre-filled from custom function) | 16/APR/2021 20:18 |
| 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

US3722338 (Prod: Keystone VitaLink Research - Greenville - PPDS)

US3722338

Form: Participant Creation

Generated On: 10 Jun 2021 09:26:23

[Participant ID](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered 'US3722338' | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 20 Aug 2020 15:55:14 |

US3722338

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:26:23

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered 'Yes (Y)' | Sara Poff (b) (4) | 20 Aug 2020 17:34:12 |

US3722338

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered '20 AUG 2020' | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 20 Aug 2020 15:55:15 |

US3722338

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|--------------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered 'Clinic (Clinic)' | Sara Poff (b) (4) | 20 Aug 2020 17:34:12 |

US3722338

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:26:23

[Folder OID](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User entered 'SCRN' | System | 20 Aug 2020 17:34:12 |

US3722338

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:26:23

Date of Birth (MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered (b) (6) 1947' | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 20 Aug 2020 15:55:16 |

US3722338

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:26:23

[Age](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered '73' | Sara Poff (b) (4) | 20 Aug 2020 17:34:25 |

US3722338

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:26:23

[Age Units](#)

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User entered 'YEARS' | System | 20 Aug 2020 17:34:25 |

US3722338

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:26:23

[Age \(Derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User entered '73' | System | 20 Aug 2020 17:34:37 |

US3722338

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:26:23

Sex

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered 'Male (M)' | Sara Poff (b) (4) | 20 Aug 2020 17:34:25 |

US3722338

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:26:23

[Ethnicity](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)' | Sara Poff (b) (4) | 20 Aug 2020 17:34:25 |

US3722338

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:26:23

White

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered 'I' | Sara Poff (b) (4) | 20 Aug 2020 17:34:25 |

US3722338

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:26:23

[Black](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered '0' | Sara Poff (b) (4) | 20 Aug 2020 17:34:25 |

US3722338

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:26:23

[Asian](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered '0' | Sara Poff (b) (4) | 20 Aug 2020 17:34:25 |

US3722338

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:26:23

[American Indian or Alaska Native](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered '0' | Sara Poff (b) (4) | 20 Aug 2020 17:34:25 |

US3722338

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:26:23

[Native Hawaiian or other Pacific Islander](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered '0' | Sara Poff (b) (4) | 20 Aug 2020 17:34:25 |

US3722338

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:26:23

[Other](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered '0' | (b) (4) Sara Poff (b) (4) (b) (4) | 20 Aug 2020 17:34:25 |

US3722338

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:26:23

If race is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered empty. | (b) (4) Sara Poff (b) (4) (b) (4) | 20 Aug 2020 17:34:25 |

US3722338

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:26:23

Unknown

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered '0' | Sara Poff (b) (4) | 20 Aug 2020 17:34:25 |

US3722338

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:26:23

[Not reported](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered '0' | Sara Poff (b) (4) | 20 Aug 2020 17:34:25 |

US3722338

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:26:23

Date of Informed Consent (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered '20 Aug 2020' | Sara Poff (b) (4) | 20 Aug 2020 17:34:37 |

US3722338

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User entered 'Aug 2020' | System | 20 Aug 2020 17:34:37 |

US3722338

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User entered '2020' | System | 20 Aug 2020 17:34:37 |

US3722338

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:26:23

[Protocol Version](#)

| Audit | User | Time (GMT) |
|---|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User closed query 'Per CDM: Protocol Version is recorded as Amendment 5, however to date there is no Amendment 5, please review and update as appropriate. Thank you' (Site from DM). | (b) (4) (b) (4), (b) (6) | 18 Sep 2020 12:40:08 |
| Query 'Per CDM: Protocol Version is recorded as Amendment 5, however to date there is no Amendment 5, please review and update as appropriate. Thank you' answered with 'completed' (Site from DM). | Kayla Peay (b) (4) (b) (4) | 17 Sep 2020 15:38:11 |
| User entered 'Amendment 2 (2)' reason for change: Data Entry Error | Kayla Peay (b) (4) (b) (4) | 17 Sep 2020 15:38:04 |
| User opened query 'Per CDM: Protocol Version is recorded as Amendment 5, however to date there is no Amendment 5, please review and update as appropriate. Thank you' (Site from DM). | (b) (4), (b) (6) | 15 Sep 2020 07:30:42 |
| User entered 'Amendment 5 (5)' | Sara Poff (b) (4) (b) (4) | 20 Aug 2020 17:34:37 |

US3722338

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered 'Yes (Y)' | Sara Poff (b) (4) | 20 Aug 2020 17:34:37 |

US3722338

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:26:23

If No, indicate reason for screen fail

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered empty. | (b) (4) Sara Poff (b) (4) (b) (4) | 20 Aug 2020 17:34:37 |

US3722338

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:26:23

If reason for screen fail is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered empty. | (b) (4) Sara Poff (b) (4) (b) (4) | 20 Aug 2020 17:34:37 |

US3722338

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:26:23

[Was this participant screened previously?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered 'No (N)' | Sara Poff (b) (4) | 20 Aug 2020 17:34:37 |

US3722338

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:26:23

[If Yes, previous participant number](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered empty. | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 20 Aug 2020 15:55:15 |

US3722338

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:26:23

[Enrollment Trigger](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User entered 'I' | System | 20 Aug 2020 17:34:41 |

US3722338

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered 'Yes (Y)' | Sara Poff (b) (4) | 20 Aug 2020 17:34:41 |

US3722338

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 09:26:23

[Were any significant conditions reported?](#)

| Audit | User | Time (GMT) |
|--|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:40:46 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| Data hard locked. | (b) (4) (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User closed query ' Per medical records received, subject had a history of Left Sided Spigelian Hernia. Since this worsened during the study requiring surgery, please consider adding this to medical history.' (Site from CRA). | (b) (4), (b) (6) | 22 Mar 2021 16:28:34 |
| Query ' Per medical records received, subject had a history of Left Sided Spigelian Hernia. Since this worsened during the study requiring surgery, please consider adding this to medical history.' answered with 'added as asked' (Site from CRA). | Sara Poff (b) (4) (b) (4) | 04 Mar 2021 01:50:40 |
| User opened query ' Per medical records received, subject had a history of Left Sided Spigelian Hernia. Since this worsened during the study requiring surgery, please consider adding this to medical history.' (Site from CRA). | (b) (4), (b) (6) | 03 Feb 2021 18:36:12 |
| Query 'Per medical records received, subject had a history of Hernia Left Lower Quadrant. Since this worsened during the study requiring surgery, please consider adding this to medical history. ' canceled (Site from CRA). | (b) (4), (b) (6) | 03 Feb 2021 18:35:43 |
| User opened query 'Per medical records received, subject had a history of Hernia Left Lower Quadrant. Since this worsened during the study requiring surgery, please consider adding this to medical history. ' (Site from CRA). | (b) (4), (b) (6) | 03 Feb 2021 17:04:48 |
| User entered 'Yes (Y)' | Kayla Peay (b) (4) (b) (4) | 20 Aug 2020 17:40:49 |

US3722338

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:26:23

[Condition](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type 2 diabetes mellitus - version MedDRA\\23.0. | (b) (4) Coder Import (b) (4) | 20 Aug 2020 17:43:26 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 20 Aug 2020 17:43:26 |
| Data point term sent to Coder | System | 20 Aug 2020 17:41:41 |
| User entered 'diabetes 2' | Kayla Peay (b) (4) | 20 Aug 2020 17:41:08 |
| | (b) (4) | |

US3722338

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered 'un UNK 1990' | Kayla Peay (b) (4) | 20 Aug 2020 17:41:08 |

US3722338

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:26:23

Start date completely unknown

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered '0' | Kayla Peay (b) (4) | 20 Aug 2020 17:41:08 |

US3722338

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:26:23

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered 'Yes (Y)' | Kayla Peay (b) (4) | 20 Aug 2020 17:41:08 |

US3722338

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered empty. | Kayla Peay (b) (4) | 20 Aug 2020 17:41:08 |

US3722338

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:26:23

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered '0' | Kayla Peay (b) (4) | 20 Aug 2020 17:41:08 |

US3722338

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User entered 'Jan 1990' | System | 20 Aug 2020 17:41:08 |

US3722338

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User entered '1990' | System | 20 Aug 2020 17:41:08 |

US3722338

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User entered empty. | System | 20 Aug 2020 17:41:08 |

US3722338

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User entered empty. | System | 20 Aug 2020 17:41:08 |

US3722338

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:26:23

Condition

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User coded data point as SOC: Vascular disorders, HLTG: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0. | Coder Import (b) (4) | 20 Aug 2020 17:43:26 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 20 Aug 2020 17:43:26 |
| Data point term sent to Coder | System | 20 Aug 2020 17:41:39 |
| User entered 'hypertension' | Kayla Peay (b) (4) | 20 Aug 2020 17:41:20 |
| | (b) (4) | |

US3722338

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered 'un UNK 2016' | Kayla Peay (b) (4) | 20 Aug 2020 17:41:20 |

US3722338

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:26:23

Start date completely unknown

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered '0' | Kayla Peay (b) (4) | 20 Aug 2020 17:41:20 |

US3722338

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:26:23

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered 'Yes (Y)' | Kayla Peay (b) (4) | 20 Aug 2020 17:41:20 |

US3722338

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered empty. | Kayla Peay (b) (4) | 20 Aug 2020 17:41:20 |

US3722338

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:26:23

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered '0' | Kayla Peay (b) (4) | 20 Aug 2020 17:41:20 |

US3722338

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User entered 'Jan 2016' | System | 20 Aug 2020 17:41:20 |

US3722338

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User entered '2016' | System | 20 Aug 2020 17:41:20 |

US3722338

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User entered empty. | System | 20 Aug 2020 17:41:20 |

US3722338

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User entered empty. | System | 20 Aug 2020 17:41:20 |

US3722338

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:26:23

[Condition](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0. | (b) (4) Coder Import (b) (4) | 20 Aug 2020 17:43:26 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 20 Aug 2020 17:43:26 |
| Data point term sent to Coder | System | 20 Aug 2020 17:41:41 |
| User entered 'hyperlipidemia' | Kayla Peay (b) (4) | 20 Aug 2020 17:41:35 |
| | (b) (4) | |

US3722338

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered 'un UNK 2016' | Kayla Peay (b) (4) | 20 Aug 2020 17:41:35 |

US3722338

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:26:23

Start date completely unknown

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered '0' | Kayla Peay (b) (4) | 20 Aug 2020 17:41:35 |

US3722338

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:26:23

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered 'Yes (Y)' | Kayla Peay (b) (4) | 20 Aug 2020 17:41:35 |

US3722338

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered empty. | Kayla Peay (b) (4) | 20 Aug 2020 17:41:35 |

US3722338

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:26:23

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered '0' | Kayla Peay (b) (4) | 20 Aug 2020 17:41:35 |

US3722338

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User entered 'Jan 2016' | System | 20 Aug 2020 17:41:35 |

US3722338

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User entered '2016' | System | 20 Aug 2020 17:41:35 |

US3722338

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User entered empty. | System | 20 Aug 2020 17:41:35 |

US3722338

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User entered empty. | System | 20 Aug 2020 17:41:35 |

US3722338

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:26:23

Condition

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User coded data point as SOC: Psychiatric disorders, HLTG: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0. | Coder Import (b) (4) | 19 Jan 2021 15:20:06 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 19 Jan 2021 15:20:06 |
| Data point term sent to Coder | System | 19 Jan 2021 15:19:18 |
| User entered 'anxiety' | Marlee Smith (b) (4) | 19 Jan 2021 15:19:04 |

US3722338

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered 'un UNK 2010' | Marlee Smith (b) (4) | 19 Jan 2021 15:19:04 |

US3722338

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:26:23

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered '0' | Marlee Smith (b) (4) | 19 Jan 2021 15:19:04 |

US3722338

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:26:23

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered 'Yes (Y)' | Marlee Smith (b) (4) | 19 Jan 2021 15:19:04 |

US3722338

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered empty. | Marlee Smith (b) (4) | 19 Jan 2021 15:19:04 |

US3722338

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:26:23

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered '0' | Marlee Smith (b) (4) | 19 Jan 2021 15:19:04 |

US3722338

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User entered 'Jan 2010' | System | 19 Jan 2021 15:19:04 |

US3722338

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User entered '2010' | System | 19 Jan 2021 15:19:04 |

US3722338

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User entered empty. | System | 19 Jan 2021 15:19:04 |

US3722338

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User entered empty. | System | 19 Jan 2021 15:19:04 |

US3722338

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:26:23

Condition

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User coded data point as SOC: Psychiatric disorders, HLTG: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0. | Coder Import (b) (4) | 19 Jan 2021 15:20:06 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 19 Jan 2021 15:20:06 |
| Data point term sent to Coder | System | 19 Jan 2021 15:19:20 |
| User entered 'insomnia' | Marlee Smith (b) (4) | 19 Jan 2021 15:19:15 |

US3722338

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered 'un UNK 2015' | Marlee Smith (b) (4) | 19 Jan 2021 15:19:15 |

US3722338

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:26:23

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered '0' | Marlee Smith (b) (4) | 19 Jan 2021 15:19:15 |

US3722338

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:26:23

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered 'Yes (Y)' | Marlee Smith (b) (4) | 19 Jan 2021 15:19:15 |

US3722338

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered empty. | Marlee Smith (b) (4) | 19 Jan 2021 15:19:15 |

US3722338

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:26:23

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered '0' | Marlee Smith (b) (4) | 19 Jan 2021 15:19:15 |

US3722338

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User entered 'Jan 2015' | System | 19 Jan 2021 15:19:15 |

US3722338

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User entered '2015' | System | 19 Jan 2021 15:19:15 |

US3722338

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User entered empty. | System | 19 Jan 2021 15:19:15 |

US3722338

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User entered empty. | System | 19 Jan 2021 15:19:15 |

US3722338

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:26:23

Condition

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Anaemias nonhaemolytic and marrow depression, HLT: Anaemias NEC, PT: Anaemia, LLT: Chronic anemia - version MedDRA\\23.0. | Coder Import (b) (4) | 19 Jan 2021 15:21:07 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 19 Jan 2021 15:21:07 |
| Data point term sent to Coder | System | 19 Jan 2021 15:20:21 |
| User entered 'chronic anemia' | Marlee Smith (b) (4) | 19 Jan 2021 15:19:29 |

US3722338

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered 'un UNK 2018' | Marlee Smith (b) (4) | 19 Jan 2021 15:19:29 |

US3722338

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:26:23

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered '0' | Marlee Smith (b) (4) | 19 Jan 2021 15:19:29 |

US3722338

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:26:23

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered 'Yes (Y)' | Marlee Smith (b) (4) | 19 Jan 2021 15:19:29 |

US3722338

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered empty. | Marlee Smith (b) (4) | 19 Jan 2021 15:19:29 |

US3722338

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:26:23

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered '0' | Marlee Smith (b) (4) | 19 Jan 2021 15:19:29 |

US3722338

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User entered 'Jan 2018' | System | 19 Jan 2021 15:19:29 |

US3722338

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User entered '2018' | System | 19 Jan 2021 15:19:29 |

US3722338

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User entered empty. | System | 19 Jan 2021 15:19:29 |

US3722338

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User entered empty. | System | 19 Jan 2021 15:19:29 |

US3722338

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:26:23

Condition

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Protein and amino acid metabolism disorders NEC, HLT: Protein metabolism disorders NEC, PT: Hypoalbuminaemia, LLT: Hypoalbuminemia - version MedDRA\\23.0. | Coder Import (b) (4) | 19 Jan 2021 15:23:07 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) | 19 Jan 2021 15:23:07 |
| Data point term sent to Coder | System | 19 Jan 2021 15:20:21 |
| User entered 'chronic hypoalbuminemia' | Marlee Smith (b) (4) | 19 Jan 2021 15:19:52 |

US3722338

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered 'un UNK 2019' | Marlee Smith (b) (4) | 19 Jan 2021 15:19:52 |

US3722338

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:26:23

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered '0' | Marlee Smith (b) (4) | 19 Jan 2021 15:19:52 |

US3722338

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:26:23

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered 'Yes (Y)' | Marlee Smith (b) (4) | 19 Jan 2021 15:19:52 |

US3722338

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered empty. | Marlee Smith (b) (4) | 19 Jan 2021 15:19:52 |

US3722338

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:26:23

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered '0' | Marlee Smith (b) (4) | 19 Jan 2021 15:19:52 |

US3722338

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User entered 'Jan 2019' | System | 19 Jan 2021 15:19:52 |

US3722338

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User entered '2019' | System | 19 Jan 2021 15:19:52 |

US3722338

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User entered empty. | System | 19 Jan 2021 15:19:52 |

US3722338

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User entered empty. | System | 19 Jan 2021 15:19:52 |

US3722338

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:26:23

Condition

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User closed query 'Per MM, please review and update the term to reflect the final diagnosis ' (Site from DM). | (b) (4) (b) (4), (b) (6) | 09 Mar 2021 09:59:12 |
| User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Dyspnoea, LLT: Dyspnea - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 03 Mar 2021 02:14:49 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 03 Mar 2021 02:14:49 |
| Data point term sent to Coder | System | 03 Mar 2021 02:14:01 |
| Query 'Per MM, please review and update the term to reflect the final diagnosis ' answered with 'Name of the med hx updated ' (Site from DM). | Sara Poff (b) (4) (b) (4) | 03 Mar 2021 02:13:58 |
| Coding entries removed. | Sara Poff (b) (4) (b) (4) | 03 Mar 2021 02:13:40 |
| User entered 'dyspnea' reason for change: Data Entry Error | Sara Poff (b) (4) (b) (4) | 03 Mar 2021 02:13:40 |
| User opened query 'Per MM, please review and update the term to reflect the final diagnosis ' (Site from DM). | (b) (4), (b) (6) | 12 Feb 2021 21:42:50 |
| User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Dyspnoea, LLT: Shortness of breath - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 19 Jan 2021 15:21:08 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 19 Jan 2021 15:21:08 |
| Data point term sent to Coder | System | 19 Jan 2021 15:20:21 |
| User entered 'shortness of breath' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:20:08 |

US3722338

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:26:23

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| Data hard locked. | (b) (4) (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| Signature has been broken. | Marlee Smith (b) (4) | 09 Mar 2021 15:21:14 |
| User entered 'UN UNK 2016' reason for change: | (b) (4) | |
| Data Entry Error | Marlee Smith (b) (4) | 09 Mar 2021 15:21:14 |
| User signature succeeded. | (b) (4) | |
| | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered 'un UNK 2017' | (b) (4) | |
| | Marlee Smith (b) (4) | 19 Jan 2021 15:20:08 |
| | (b) (4) | |

US3722338

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:26:23

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered '0' | Marlee Smith (b) (4) | 19 Jan 2021 15:20:08 |

US3722338

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:26:23

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered 'Yes (Y)' | Marlee Smith (b) (4) | 19 Jan 2021 15:20:08 |

US3722338

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered empty. | Marlee Smith (b) (4) | 19 Jan 2021 15:20:08 |

US3722338

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:26:23

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered '0' | Marlee Smith (b) (4) | 19 Jan 2021 15:20:08 |

US3722338

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User entered 'Jan 2016' | System | 09 Mar 2021 15:21:14 |
| User entered 'Jan 2017' | System | 19 Jan 2021 15:20:08 |

US3722338

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User entered '2016' | System | 09 Mar 2021 15:21:14 |
| User entered '2017' | System | 19 Jan 2021 15:20:08 |

US3722338

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User entered empty. | System | 19 Jan 2021 15:20:08 |

US3722338

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User entered empty. | System | 19 Jan 2021 15:20:08 |

US3722338

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:26:23

[Condition](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0. | Coder Import (b) (4) | 19 Jan 2021 15:22:09 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 19 Jan 2021 15:22:09 |
| Data point term sent to Coder | System | 19 Jan 2021 15:21:23 |
| User entered 'seasonal allergies' | Marlee Smith (b) (4) | 19 Jan 2021 15:20:23 |

US3722338

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:26:23

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| Data hard locked. | (b) (4) (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| Signature has been broken. | Marlee Smith (b) (4) | 09 Mar 2021 20:03:33 |
| User entered 'UN UNK 2016' reason for change: | (b) (4) | |
| Data Entry Error | Marlee Smith (b) (4) | 09 Mar 2021 20:03:33 |
| User signature succeeded. | (b) (4) | |
| | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered 'un UNK 2018' | (b) (4) | |
| | Marlee Smith (b) (4) | 19 Jan 2021 15:20:23 |
| | (b) (4) | |

US3722338

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:26:23

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered '0' | Marlee Smith (b) (4) | 19 Jan 2021 15:20:23 |

US3722338

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:26:23

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered 'Yes (Y)' | Marlee Smith (b) (4) | 19 Jan 2021 15:20:23 |

US3722338

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered empty. | Marlee Smith (b) (4) | 19 Jan 2021 15:20:23 |

US3722338

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:26:23

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered '0' | Marlee Smith (b) (4) | 19 Jan 2021 15:20:23 |

US3722338

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User entered 'Jan 2016' | System | 09 Mar 2021 20:03:33 |
| User entered 'Jan 2018' | System | 19 Jan 2021 15:20:23 |

US3722338

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User entered '2016' | System | 09 Mar 2021 20:03:33 |
| User entered '2018' | System | 19 Jan 2021 15:20:23 |

US3722338

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User entered empty. | System | 19 Jan 2021 15:20:23 |

US3722338

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User entered empty. | System | 19 Jan 2021 15:20:23 |

US3722338

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:26:23

Condition

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User closed query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis) and the location. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. | (b) (4) (b) (4), (b) (6) | 08 Mar 2021 14:10:06 |
| ' (Site from DM). | | |
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis knees - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 04 Mar 2021 22:24:42 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 04 Mar 2021 22:24:42 |
| Query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis) and the location. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. | Sara Poff (b) (4) (b) (4) | 03 Mar 2021 02:15:05 |
| ' answered with 'Updated to corrected name per subject ' (Site from DM). | | |
| Data point term sent to Coder | System | 03 Mar 2021 02:15:02 |
| Coding entries removed. | Sara Poff (b) (4) (b) (4) | 03 Mar 2021 02:14:48 |
| User entered 'Osteoarthritis ARTHRITIS in bilateral Knees' reason for change: Data Entry Error | Sara Poff (b) (4) (b) (4) | 03 Mar 2021 02:14:48 |
| User opened query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis) and the location. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. | (b) (4), (b) (6) | 22 Feb 2021 05:25:44 |
| ' (Site from DM). | | |

US3722338

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:26:23

Condition

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Arthropathies NEC, PT: Arthritis, LLT: Arthritis - version MedDRA\\23.0. | Coder Import (b) (4) | 19 Jan 2021 15:22:07 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 19 Jan 2021 15:22:07 |
| Data point term sent to Coder | System | 19 Jan 2021 15:21:23 |
| User entered 'arthritis' | Marlee Smith (b) (4) | 19 Jan 2021 15:20:39 |
| | (b) (4) | |

US3722338

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered 'un UNK 2015' | Marlee Smith (b) (4) | 19 Jan 2021 15:20:39 |

US3722338

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:26:23

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered '0' | Marlee Smith (b) (4) | 19 Jan 2021 15:20:39 |

US3722338

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:26:23

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered 'Yes (Y)' | Marlee Smith (b) (4) | 19 Jan 2021 15:20:39 |

US3722338

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered empty. | Marlee Smith (b) (4) | 19 Jan 2021 15:20:39 |

US3722338

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:26:23

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered '0' | Marlee Smith (b) (4) | 19 Jan 2021 15:20:39 |

US3722338

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User entered 'Jan 2015' | System | 19 Jan 2021 15:20:39 |

US3722338

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User entered '2015' | System | 19 Jan 2021 15:20:39 |

US3722338

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User entered empty. | System | 19 Jan 2021 15:20:39 |

US3722338

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User entered empty. | System | 19 Jan 2021 15:20:39 |

US3722338

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:26:23

[Condition](#)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User coded data point as SOC: Vascular disorders, HLTG: Embolism and thrombosis, HLT: Peripheral embolism and thrombosis, PT: Thrombophlebitis superficial, LLT: Superficial thrombophlebitis - version MedDRA\\23.0. | Coder Import (b) (4) | 19 Jan 2021 15:22:06 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 19 Jan 2021 15:22:06 |
| Data point term sent to Coder | System | 19 Jan 2021 15:21:23 |
| User entered 'superficial thrombophlebitis' | Marlee Smith (b) (4) | 19 Jan 2021 15:21:00 |

US3722338

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered 'un UNK 2018' | Marlee Smith (b) (4) | 19 Jan 2021 15:21:00 |

US3722338

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:26:23

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered '0' | Marlee Smith (b) (4) | 19 Jan 2021 15:21:00 |

US3722338

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:26:23

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered 'Yes (Y)' | Marlee Smith (b) (4) | 19 Jan 2021 15:21:00 |

US3722338

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered empty. | Marlee Smith (b) (4) | 19 Jan 2021 15:21:00 |

US3722338

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:26:23

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered '0' | Marlee Smith (b) (4) | 19 Jan 2021 15:21:00 |

US3722338

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User entered 'Jan 2018' | System | 19 Jan 2021 15:21:00 |

US3722338

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User entered '2018' | System | 19 Jan 2021 15:21:00 |

US3722338

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User entered empty. | System | 19 Jan 2021 15:21:00 |

US3722338

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User entered empty. | System | 19 Jan 2021 15:21:00 |

US3722338

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:26:23

Condition

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User coded data point as SOC: Vascular disorders, HLT: Varicose veins NEC, PT: Varicose vein, LLT: Varicose veins - version MedDRA\\23.0. | Coder Import (b) (4) | 19 Jan 2021 15:22:08 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 19 Jan 2021 15:22:08 |
| Data point term sent to Coder | System | 19 Jan 2021 15:21:23 |
| User entered 'varicose veins' | Marlee Smith (b) (4) | 19 Jan 2021 15:21:14 |

US3722338

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered 'un UNK 2016' | Marlee Smith (b) (4) | 19 Jan 2021 15:21:14 |

US3722338

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:26:23

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered '0' | Marlee Smith (b) (4) | 19 Jan 2021 15:21:14 |

US3722338

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:26:23

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered 'Yes (Y)' | Marlee Smith (b) (4) | 19 Jan 2021 15:21:14 |

US3722338

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered empty. | Marlee Smith (b) (4) | 19 Jan 2021 15:21:14 |

US3722338

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:26:23

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered '0' | Marlee Smith (b) (4) | 19 Jan 2021 15:21:14 |

US3722338

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User entered 'Jan 2016' | System | 19 Jan 2021 15:21:14 |

US3722338

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User entered '2016' | System | 19 Jan 2021 15:21:14 |

US3722338

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User entered empty. | System | 19 Jan 2021 15:21:14 |

US3722338

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User entered empty. | System | 19 Jan 2021 15:21:14 |

US3722338

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:26:23

Condition

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 14:47:11 |
| User coded data point as SOC: Gastrointestinal disorders, HLGT: Abdominal hernias and other abdominal wall conditions, HLT: Abdominal hernias NEC, PT: Abdominal hernia, LLT: Abdominal hernia - version MedDRA\\23.0. | Coder Import (b) (4) | 08 Apr 2021 06:11:42 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) | 08 Apr 2021 06:11:42 |
| Data point term sent to Coder | System | 07 Apr 2021 17:17:01 |
| User entered 'Hernia left lower quadrant' | Marlee Smith (b) (4) | 07 Apr 2021 17:16:43 |
| | (b) (4) | |

US3722338

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:26:23

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 14:47:11 |
| User entered 'un UNK 2003' | Marlee Smith (b) (4) | 07 Apr 2021 17:16:43 |

US3722338

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:26:23

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 14:47:11 |
| User entered '0' | Marlee Smith (b) (4) | 07 Apr 2021 17:16:43 |

US3722338

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:26:23

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 14:47:11 |
| User entered 'Yes (Y)' | Marlee Smith (b) (4) | 07 Apr 2021 17:16:43 |

US3722338

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 14:47:11 |
| User entered empty. | Marlee Smith (b) (4) | 07 Apr 2021 17:16:43 |

US3722338

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:26:23

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 14:47:11 |
| User entered '0' | Marlee Smith (b) (4) | 07 Apr 2021 17:16:43 |

US3722338

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User entered 'Jan 2003' | System | 07 Apr 2021 17:16:43 |

US3722338

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User entered '2003' | System | 07 Apr 2021 17:16:43 |

US3722338

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User entered empty. | System | 07 Apr 2021 17:16:43 |

US3722338

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:19:41 |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 09:41:00 |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User entered empty. | System | 07 Apr 2021 17:16:43 |

US3722338

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:26:23

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered 'Yes (Y)' | Kayla Peay (b) (4) | 20 Aug 2020 17:42:51 |

US3722338

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:26:23

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered '20 Aug 2020' | (b) (4) Kayla Peay (b) (4) (b) (4) | 20 Aug 2020 17:42:51 |

US3722338

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered '12:05' | Kayla Peay (b) (4) | 20 Aug 2020 17:42:51 |

US3722338

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User entered '20 Aug 2020 12:05' | System | 20 Aug 2020 17:42:51 |

US3722338

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered '68' in | (b) (4) Kayla Peay (b) (4) | 20 Aug 2020 17:42:51 |
| DataPoint set to visible. | (b) (4) System | 20 Aug 2020 17:34:41 |

US3722338

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:26:23

Weight (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered '266' lb | (b) (4) Kayla Peay (b) (4) | 20 Aug 2020 17:42:51 |
| DataPoint set to visible. | (b) (4) System | 20 Aug 2020 17:34:41 |

US3722338

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:26:23

BMI (xxx.x)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| Amendment Manager: User entered '40.52973' | System | 17 Sep 2020 00:16:08 |
| User entered '40.5' | System | 20 Aug 2020 17:42:51 |
| DataPoint set to visible. | System | 20 Aug 2020 17:34:41 |

US3722338

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:26:23

[BMI units](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User entered 'kg/m2' | System | 20 Aug 2020 17:42:51 |
| DataPoint set to visible. | System | 20 Aug 2020 17:34:41 |

US3722338

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:26:23

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4) | 09 Sep 2020 14:48:10 |
| User entered '98.5' F | Kayla Peay (b) (4) | 20 Aug 2020 17:42:51 |
| | (b) (4) | |

US3722338

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:26:23

[Route of measurement](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered empty; reason for change Data Entry Error | (b) (4) | 09 Sep 2020 14:48:10 |
| User entered 'Oral (Oral)' | Kayla Peay (b) (4) | 20 Aug 2020 17:42:51 |
| | (b) (4) | |

US3722338

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:26:23

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered empty. | Kayla Peay (b) (4) | 20 Aug 2020 17:42:51 |

US3722338

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:26:23

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4) | 09 Sep 2020 14:48:10 |
| User entered '86' | Kayla Peay (b) (4) | 20 Aug 2020 17:42:51 |
| | (b) (4) | |

US3722338

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:26:23

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User entered 'bpm' | System | 20 Aug 2020 17:42:51 |

US3722338

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4) | 09 Sep 2020 14:48:10 |
| User entered '17' | Kayla Peay (b) (4) | 20 Aug 2020 17:42:51 |
| | (b) (4) | |

US3722338

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:26:23

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User entered 'breaths/min' | System | 20 Aug 2020 17:42:51 |

US3722338

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4) | 09 Sep 2020 14:48:10 |
| User entered '140' | Kayla Peay (b) (4) | 20 Aug 2020 17:42:51 |
| | (b) (4) | |

US3722338

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:26:23

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User entered 'mmHg' | System | 20 Aug 2020 17:42:51 |

US3722338

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:26:23

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4) | 09 Sep 2020 14:48:10 |
| User entered '67' | Kayla Peay (b) (4) | 20 Aug 2020 17:42:51 |
| | (b) (4) | |

US3722338

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:26:23

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User entered 'mmHg' | System | 20 Aug 2020 17:42:51 |

US3722338

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:26:23

[Height \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |

US3722338

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:26:23

Weight (derived)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |

US3722338

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:26:23

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered 'Yes (Y)' | Kayla Peay (b) (4) | 20 Aug 2020 17:42:58 |

US3722338

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:26:23

Date of examination (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered '20 Aug 2020' | Kayla Peay (b) (4) | 20 Aug 2020 17:42:58 |

US3722338

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:26:23

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered 'No (N)' | (b) (4) Sara Poff (b) (4) (b) (4) | 20 Aug 2020 17:35:03 |

US3722338

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:26:23

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered 'No (N)' | (b) (4) Sara Poff (b) (4) (b) (4) | 20 Aug 2020 17:35:03 |

US3722338

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:26:23

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered 'No (N)' | Sara Poff (b) (4) | 20 Aug 2020 17:35:03 |

US3722338

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:26:23

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered 'No (N)' | Sara Poff (b) (4) | 20 Aug 2020 17:35:03 |

US3722338

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:26:23

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered 'No (N)' | Sara Poff (b) (4) | 20 Aug 2020 17:35:03 |

US3722338

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:26:23

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered 'No (N)' | Sara Poff (b) (4) | 20 Aug 2020 17:35:03 |

US3722338

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:26:23

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered 'No (N)' | Sara Poff (b) (4) | 20 Aug 2020 17:35:03 |

US3722338

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:26:23

[Personal Care and in-home services](#) (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered 'No (N)' | Sara Poff (b) (4) | 20 Aug 2020 17:35:03 |

US3722338

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:26:23

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered 'No (N)' | Sara Poff (b) (4) | 20 Aug 2020 17:35:03 |

US3722338

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:26:23

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered 'No (N)' | Sara Poff (b) (4) | 20 Aug 2020 17:35:03 |

US3722338

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:26:23

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered 'No (N)' | Sara Poff (b) (4) | 20 Aug 2020 17:35:03 |

US3722338

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:26:23

[Other](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered 'No (N)' | Sara Poff (b) (4) | 20 Aug 2020 17:35:03 |

US3722338

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:26:23

[Specify](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered empty. | (b) (4) Sara Poff (b) (4) (b) (4) | 20 Aug 2020 17:35:03 |

US3722338

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:26:23

No Risk Identified

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered '0' | Sara Poff (b) (4) | 20 Aug 2020 17:35:03 |

US3722338

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered '0' | Sara Poff (b) (4) | 20 Aug 2020 17:35:03 |

US3722338

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:26:23

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered '0' | Sara Poff (b) (4) | 20 Aug 2020 17:35:03 |

US3722338

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:26:23

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered '0' | (b) (4) Sara Poff (b) (4) (b) (4) | 20 Aug 2020 17:35:03 |

US3722338

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:26:23

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered '0' | Sara Poff (b) (4) | 20 Aug 2020 17:35:03 |

US3722338

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered 'I' | (b) (4) Sara Poff (b) (4) (b) (4) | 20 Aug 2020 17:35:03 |

US3722338

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:26:23

[Other](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered '0' | Sara Poff (b) (4) | 20 Aug 2020 17:35:03 |

US3722338

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:26:23

[Specify](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered empty. | (b) (4) Sara Poff (b) (4) (b) (4) | 20 Aug 2020 17:35:03 |

US3722338

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:26:23

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:44:34 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered 'Yes (Y)' | Sara Poff (b) (4) | 20 Aug 2020 17:35:18 |

US3722338

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:44:34 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered '20 Aug 2020' | Sara Poff (b) (4) | 20 Aug 2020 17:35:18 |

US3722338

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|--------------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:44:34 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered 'Clinic (Clinic)' | Sara Poff (b) (4) | 20 Aug 2020 17:35:18 |

US3722338

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:26:23

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:44:34 |
| User entered 'VISIT1' | System | 20 Aug 2020 17:35:18 |

US3722338

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:44:34 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered '20 AUG 2020' | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 20 Aug 2020 16:44:24 |

US3722338

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:26:23

[What was the participant's randomization number?](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:44:34 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System). | (b) (4) System | 21 Aug 2020 05:53:19 |
| Amendment Manager: Data point set to conformant. | System | 21 Aug 2020 05:53:19 |
| User opened query 'Data entered is non-conformant. Please correct.' (Site from System). | System | 20 Aug 2020 16:44:24 |
| User entered '187125' (non-conformant). | RWS_ENDPOINT ENDPOINT (b) (4) | 20 Aug 2020 16:44:24 |

US3722338

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|-------------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:44:34 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered '>=65 years (3)' | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 20 Aug 2020 16:44:24 |

US3722338

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:26:23

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:44:34 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered 'No (N)' | Sara Poff (b) (4) | 20 Aug 2020 17:35:43 |

US3722338

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:26:23

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:44:34 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered 'No (N)' | Sara Poff (b) (4) | 20 Aug 2020 17:35:43 |

US3722338

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:44:34 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered 'Yes (Y)' | Sara Poff (b) (4) | 20 Aug 2020 17:35:43 |

US3722338

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:26:23

Diabetes (Type I, Type 2, or gestational)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:44:34 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered 'Yes (Y)' | Sara Poff (b) (4) | 20 Aug 2020 17:35:43 |

US3722338

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:26:23

[Liver Disease](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:44:34 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered 'No (N)' | Sara Poff (b) (4) | 20 Aug 2020 17:35:43 |

US3722338

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:26:23

Human Immunodeficiency Virus (HIV) infection

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:44:34 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User closed query 'Per CDM: Please input yes or no in this field.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 22 Dec 2020 15:54:12 |
| Query 'Per CDM: Please input yes or no in this field.' answered with 'updated' (Site from DM). | Marlee Smith (b) (4) | 21 Dec 2020 20:03:58 |
| User entered 'No (N)' | (b) (4) Marlee Smith (b) (4) | 21 Dec 2020 20:03:53 |
| User opened query 'Per CDM: Please input yes or no in this field.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 18 Dec 2020 17:33:52 |
| Amendment Manager: DataPoint set to visible. | System | 19 Sep 2020 10:36:59 |
| Amendment Manager inserted this DataPoint. | System | 19 Sep 2020 01:45:26 |

US3722338

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:26:23

[Height](#)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:44:34 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4) | 09 Sep 2020 14:48:20 |
| User entered '68' in | Kayla Peay (b) (4) | 20 Aug 2020 17:44:04 |
| | (b) (4) | |

US3722338

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:26:23

Weight

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:44:34 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4) | 09 Sep 2020 14:48:20 |
| User entered '266' lb | Kayla Peay (b) (4) | 20 Aug 2020 17:44:04 |
| | (b) (4) | |

US3722338

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:26:23

[Height](#)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:44:34 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4) | 09 Sep 2020 14:48:20 |
| User entered '68' in | Kayla Peay (b) (4) | 20 Aug 2020 17:44:04 |
| | (b) (4) | |

US3722338

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:26:23

Weight

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:44:34 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4) | 09 Sep 2020 14:48:20 |
| User entered '266' lb | Kayla Peay (b) (4) | 20 Aug 2020 17:44:04 |
| | (b) (4) | |

US3722338

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:26:23

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:44:34 |
| User accepted default value 'Pre-Dose (PREDOSE)' | Kayla Peay (b) (4) (b) (4) | 20 Aug 2020 17:44:04 |

US3722338

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:26:23

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:44:34 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered 'Yes (Y)' | Kayla Peay (b) (4) | 20 Aug 2020 17:44:04 |

US3722338

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:26:23

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:44:34 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered '20 Aug 2020' | Kayla Peay (b) (4) | 20 Aug 2020 17:44:04 |

US3722338

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:44:34 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered '12:05' | Kayla Peay (b) (4) | 20 Aug 2020 17:44:04 |

US3722338

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:44:34 |
| User entered '20 Aug 2020 12:05' | System | 20 Aug 2020 17:44:04 |

US3722338

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:26:23

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:44:34 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered '98.5' F | Kayla Peay (b) (4) | 20 Aug 2020 17:44:04 |

US3722338

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:26:23

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:44:34 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered 'Oral (Oral)' | Kayla Peay (b) (4) | 20 Aug 2020 17:44:04 |

US3722338

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:26:23

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:44:34 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered empty. | Kayla Peay (b) (4) | 20 Aug 2020 17:44:04 |

US3722338

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:26:23

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:44:34 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered '86' | Kayla Peay (b) (4) | 20 Aug 2020 17:44:04 |

US3722338

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:26:23

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:44:34 |
| User entered 'bpm' | System | 20 Aug 2020 17:44:04 |

US3722338

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:44:34 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered '17' | Kayla Peay (b) (4) | 20 Aug 2020 17:44:04 |

US3722338

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:26:23

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:44:34 |
| User entered 'breaths/min' | System | 20 Aug 2020 17:44:04 |

US3722338

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:26:23

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:44:34 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered '140' | Kayla Peay (b) (4) | 20 Aug 2020 17:44:04 |

US3722338

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:26:23

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:44:34 |
| User entered 'mmHg' | System | 20 Aug 2020 17:44:04 |

US3722338

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:26:23

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:44:34 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered '67' | Kayla Peay (b) (4) | 20 Aug 2020 17:44:04 |

US3722338

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:26:23

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:44:34 |
| User entered 'mmHg' | System | 20 Aug 2020 17:44:04 |

US3722338

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:26:23

[Height](#)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:44:34 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4) | 09 Sep 2020 14:48:20 |
| User entered '68' in | Kayla Peay (b) (4) | 20 Aug 2020 17:44:04 |
| | (b) (4) | |

US3722338

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:26:23

Weight

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:44:34 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4) | 09 Sep 2020 14:48:20 |
| User entered '266' lb | Kayla Peay (b) (4) | 20 Aug 2020 17:44:04 |
| | (b) (4) | |

US3722338

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:26:23

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:44:34 |
| User accepted default value 'Post-Dose (POSTDOSE)' | Kayla Peay (b) (4) (b) (4) | 20 Aug 2020 17:44:04 |

US3722338

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:26:23

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:44:34 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered 'Yes (Y)' | Kayla Peay (b) (4) | 20 Aug 2020 17:44:04 |

US3722338

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:26:23

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:44:34 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered '20 Aug 2020' | Kayla Peay (b) (4) | 20 Aug 2020 17:44:04 |

US3722338

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:44:34 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| Amendment Manager: Query closed during migration process because the edit check no longer exists in target version. | (b) (4) | 21 Aug 2020 05:53:16 |
| User opened 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). | System | 20 Aug 2020 20:38:32 |
| User closed query 'Data is required. Please provide.' (Site from System). | System | 20 Aug 2020 20:38:32 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). | System | 20 Aug 2020 20:38:32 |
| User entered '13:35' reason for change: Data Entry Error | Kayla Peay (b) (4) | 20 Aug 2020 20:38:32 |
| User opened query 'Data is required. Please provide.' (Site from System). | (b) (4) | 20 Aug 2020 17:44:04 |
| User entered empty. | Kayla Peay (b) (4) | 20 Aug 2020 17:44:04 |
| | (b) (4) | |

US3722338

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:44:34 |
| User entered '20 Aug 2020 13:35' | System | 20 Aug 2020 20:38:32 |
| User entered empty. | System | 20 Aug 2020 17:44:04 |

US3722338

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:26:23

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:44:34 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4) System | 20 Aug 2020 20:38:32 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). | | 20 Aug 2020 20:38:32 |
| User entered '97.7' F reason for change: Data Entry Error | Kayla Peay (b) (4) | 20 Aug 2020 20:38:32 |
| User opened query 'Data is required. Please provide.' (Site from System). | (b) (4) System | 20 Aug 2020 17:44:04 |
| User entered empty. | Kayla Peay (b) (4) | 20 Aug 2020 17:44:04 |
| | (b) (4) | |

US3722338

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:26:23

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:44:34 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered 'Oral (Oral)' | Kayla Peay (b) (4) | 20 Aug 2020 17:44:04 |

US3722338

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:26:23

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:44:34 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered empty. | Kayla Peay (b) (4) | 20 Aug 2020 17:44:04 |

US3722338

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:26:23

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:44:34 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4) System | 20 Aug 2020 20:38:32 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). | | 20 Aug 2020 20:38:32 |
| User entered '72' reason for change: Data Entry Error | Kayla Peay (b) (4) | 20 Aug 2020 20:38:32 |
| User opened query 'Data is required. Please provide.' (Site from System). | (b) (4) System | 20 Aug 2020 17:44:04 |
| User entered empty. | Kayla Peay (b) (4) | 20 Aug 2020 17:44:04 |
| | (b) (4) | |

US3722338

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:26:23

[Pulse units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:44:34 |
| User entered 'bpm' | System | 20 Aug 2020 20:38:32 |
| User entered empty. | System | 20 Aug 2020 17:44:04 |

US3722338

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:44:34 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4) System | 20 Aug 2020 20:38:32 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). | | 20 Aug 2020 20:38:32 |
| User entered '18' reason for change: Data Entry Error | Kayla Peay (b) (4) | 20 Aug 2020 20:38:32 |
| User opened query 'Data is required. Please provide.' (Site from System). | (b) (4) System | 20 Aug 2020 17:44:04 |
| User entered empty. | Kayla Peay (b) (4) | 20 Aug 2020 17:44:04 |
| | (b) (4) | |

US3722338

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:26:23

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:44:34 |
| User entered 'breaths/min' | System | 20 Aug 2020 20:38:32 |
| User entered empty. | System | 20 Aug 2020 17:44:04 |

US3722338

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:26:23

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:44:34 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4) System | 20 Aug 2020 20:38:32 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). | | 20 Aug 2020 20:38:32 |
| User entered '133' reason for change: Data Entry Error | Kayla Peay (b) (4) | 20 Aug 2020 20:38:32 |
| User opened query 'Data is required. Please provide.' (Site from System). | (b) (4) System | 20 Aug 2020 17:44:04 |
| User entered empty. | Kayla Peay (b) (4) | 20 Aug 2020 17:44:04 |
| | (b) (4) | |

US3722338

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:26:23

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:44:34 |
| User entered 'mmHg' | System | 20 Aug 2020 20:38:32 |
| User entered empty. | System | 20 Aug 2020 17:44:04 |

US3722338

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:26:23

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:44:34 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4) System | 20 Aug 2020 20:38:32 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). | | 20 Aug 2020 20:38:32 |
| User entered '70' reason for change: Data Entry Error | Kayla Peay (b) (4) | 20 Aug 2020 20:38:32 |
| User opened query 'Data is required. Please provide.' (Site from System). | (b) (4) System | 20 Aug 2020 17:44:04 |
| User entered empty. | Kayla Peay (b) (4) | 20 Aug 2020 17:44:04 |
| | (b) (4) | |

US3722338

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:26:23

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:44:34 |
| User entered 'mmHg' | System | 20 Aug 2020 20:38:32 |
| User entered empty. | System | 20 Aug 2020 17:44:04 |

US3722338

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:26:23

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:44:34 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered 'No (N)' reason for change: Data Entry Error | Kayla Peay (b) (4) | 09 Sep 2020 14:48:28 |
| User entered 'Yes (Y)' | Kayla Peay (b) (4) | 20 Aug 2020 17:44:12 |

US3722338

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:26:23

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:44:34 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered empty; reason for change Data Entry Error | Kayla Peay (b) (4) | 09 Sep 2020 14:48:28 |
| User entered '20 Aug 2020' | Kayla Peay (b) (4) | 20 Aug 2020 17:44:12 |

US3722338

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:26:23

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:44:34 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered 'Yes (Y)' | Sara Poff (b) (4) | 20 Aug 2020 17:36:06 |

US3722338

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:26:23

[If No, reason not given](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:44:34 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered empty. | Sara Poff (b) (4) | 20 Aug 2020 17:36:06 |

US3722338

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:44:34 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered empty. | Sara Poff (b) (4) | 20 Aug 2020 17:36:06 |

US3722338

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:26:23

[What was the study treatment?](#)

| Audit | User | Time (GMT) |
|-------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:44:34 |
| User entered 'MRNA-1273 OR PLACEBO' | System | 20 Aug 2020 17:36:06 |

US3722338

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:26:23

What was the treatment date? (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:44:34 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered '20 Aug 2020' | Sara Poff (b) (4) | 20 Aug 2020 17:36:06 |

US3722338

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:44:34 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered '13:05' | Sara Poff (b) (4) | 20 Aug 2020 17:36:06 |

US3722338

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:44:34 |
| User entered '20 Aug 2020 13:05' | System | 20 Aug 2020 17:36:06 |

US3722338

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|------------------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:44:34 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered 'Left Arm (LEFT ARM)' | Sara Poff (b) (4) | 20 Aug 2020 17:36:06 |

US3722338

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:44:34 |
| User entered 'ONCE' | System | 20 Aug 2020 17:36:06 |

US3722338

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:26:23

What was the route of administration for the study treatment?

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:44:34 |
| User entered 'INTRAMUSCULAR' | System | 20 Aug 2020 17:36:06 |

US3722338

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:26:23

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:44:34 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered 'Yes (Y)' | Kayla Peay (b) (4) | 20 Aug 2020 17:44:25 |

US3722338

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:26:23

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:44:34 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered '20 Aug 2020' | Kayla Peay (b) (4) | 20 Aug 2020 17:44:25 |

US3722338

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:26:23

Collection time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:44:34 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered '12:35' | Kayla Peay (b) (4) | 20 Aug 2020 17:44:25 |

US3722338

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:26:23

Collection date and time (derived)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:44:34 |
| User entered '20 Aug 2020 12:35' | System | 20 Aug 2020 17:44:25 |

US3722338

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:26:23

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:44:34 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered '20 Aug 2020' | Kayla Peay (b) (4) | 20 Aug 2020 17:44:42 |

US3722338

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:26:23

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:44:34 |
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | Kayla Peay (b) (4) (b) (4) | 20 Aug 2020 17:44:42 |

US3722338

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:26:23

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:44:34 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered 'Yes (Y)' | Kayla Peay (b) (4) | 20 Aug 2020 17:44:42 |

US3722338

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:26:23

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:44:34 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered '12:19' | Kayla Peay (b) (4) | 20 Aug 2020 17:44:42 |

US3722338

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:26:23

Collection date and time (derived)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:44:34 |
| User entered '20 Aug 2020 12:19' | System | 20 Aug 2020 17:44:42 |

US3722338

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:26:23

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:44:34 |
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | Kayla Peay (b) (4) (b) (4) | 20 Aug 2020 17:44:42 |

US3722338

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:26:23

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:44:34 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered 'Yes (Y)' | Kayla Peay (b) (4) | 20 Aug 2020 17:44:42 |

US3722338

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:26:23

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:44:34 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered '12:19' | Kayla Peay (b) (4) | 20 Aug 2020 17:44:42 |

US3722338

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:26:23

Collection date and time (derived)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:44:34 |
| User entered '20 Aug 2020 12:19' | System | 20 Aug 2020 17:44:42 |

US3722338

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:26:23

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:44:34 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered 'Yes (Y)' | Kayla Peay (b) (4) | 20 Aug 2020 17:37:35 |

US3722338

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:26:23

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:44:34 |
| User entered 'I' | System | 20 Aug 2020 17:37:35 |

US3722338

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| Data entry locked. | System | 20 Aug 2020 17:36:06 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 20 Aug 2020 17:36:06 |

US3722338

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:26:23

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-20T13:37:20', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'c008ef3a-24f2-4717-b0a1-e2a304149ff3' | System | 20 Aug 2020 17:37:54 |
| User entered 'Yes (Y)' | System | 20 Aug 2020 17:37:54 |

US3722338

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:26:23

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-20T13:37:35', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'c008ef3a-24f2-4717-b0a1-e2a304149ff3' | System | 20 Aug 2020 17:37:54 |
| User entered '97.7' | System | 20 Aug 2020 17:37:54 |

US3722338

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-20T13:37:41', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'c008ef3a-24f2-4717-b0a1-e2a304149ff3' | System | 20 Aug 2020 17:37:54 |
| User entered 'No (N)' | System | 20 Aug 2020 17:37:54 |

US3722338

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:26:23

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-20T13:37:50', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'c008ef3a-24f2-4717-b0a1-e2a304149ff3' | System | 20 Aug 2020 17:37:54 |
| User entered '20 Aug 2020 13:37' | System | 20 Aug 2020 17:37:54 |

US3722338

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:26:23

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| User entered '20 Aug 2020 13:25' | System | 20 Aug 2020 17:36:06 |

US3722338

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:26:23

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| User entered '20 Aug 2020 15:55' | System | 20 Aug 2020 17:36:06 |

US3722338

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| Data entry locked. | System | 20 Aug 2020 17:36:06 |
| User entered 'Day 1, after vaccination (at home)' | System | 20 Aug 2020 17:36:06 |

US3722338

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:26:23

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| | | |

US3722338

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:26:23

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| | | |

US3722338

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| | | |

US3722338

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| | | |

US3722338

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:26:23

To **PREVENT** pain or fever from occurring

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| | | |

US3722338

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:26:23

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| | | |

US3722338

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:26:23

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| User entered '20 Aug 2020 16:50' | System | 20 Aug 2020 17:36:06 |

US3722338

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:26:23

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| User entered '21 Aug 2020 11:59' | System | 20 Aug 2020 17:36:06 |

US3722338

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| Data entry locked. | System | 20 Aug 2020 17:36:06 |
| User entered 'Day 2' | System | 20 Aug 2020 17:36:06 |

US3722338

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:26:23

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-21T14:01:30', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '0762dfae-b0a2-47a2-a157-6708107ee0af' | System | 21 Aug 2020 18:01:55 |
| User entered 'Yes (Y)' | System | 21 Aug 2020 18:01:55 |

US3722338

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:26:23

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-21T14:01:39', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '0762dfae-b0a2-47a2-a157-6708107ee0af' | System | 21 Aug 2020 18:01:55 |
| User entered '97.5' | System | 21 Aug 2020 18:01:55 |

US3722338

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-21T14:01:44', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '0762dfae-b0a2-47a2-a157-6708107ee0af' | System | 21 Aug 2020 18:01:55 |
| User entered 'No (N)' | System | 21 Aug 2020 18:01:55 |

US3722338

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:26:23

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-21T14:01:50', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '0762dfae-b0a2-47a2-a157-6708107ee0af' | System | 21 Aug 2020 18:01:55 |
| User entered '21 Aug 2020 14:01' | System | 21 Aug 2020 18:01:55 |

US3722338

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:26:23

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| User entered '21 Aug 2020 12:00' | System | 20 Aug 2020 17:36:06 |

US3722338

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:26:23

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| User entered '22 Aug 2020 11:59' | System | 20 Aug 2020 17:36:06 |

US3722338

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| Data entry locked. | System | 20 Aug 2020 17:36:06 |
| User entered 'Day 3' | System | 20 Aug 2020 17:36:06 |

US3722338

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:26:23

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-22T20:44:43', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'cb14df25-3af2-46cb-9b45-4dce9c306b1b' | System | 23 Aug 2020 00:45:08 |
| User entered 'Yes (Y)' | System | 23 Aug 2020 00:45:08 |

US3722338

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:26:23

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-22T20:44:53', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'cb14df25-3af2-46cb-9b45-4dce9c306b1b' | System | 23 Aug 2020 00:45:08 |
| User entered '97.9' | System | 23 Aug 2020 00:45:08 |

US3722338

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-22T20:44:57', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'cb14df25-3af2-46cb-9b45-4dce9c306b1b' | System | 23 Aug 2020 00:45:08 |
| User entered 'No (N)' | System | 23 Aug 2020 00:45:08 |

US3722338

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:26:23

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-22T20:45:04', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'cb14df25-3af2-46cb-9b45-4dce9c306b1b' | System | 23 Aug 2020 00:45:08 |
| User entered '22 Aug 2020 20:45' | System | 23 Aug 2020 00:45:08 |

US3722338

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:26:23

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| User entered '22 Aug 2020 12:00' | System | 20 Aug 2020 17:36:06 |

US3722338

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:26:23

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| User entered '23 Aug 2020 11:59' | System | 20 Aug 2020 17:36:06 |

US3722338

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| Data entry locked. | System | 20 Aug 2020 17:36:06 |
| User entered 'Day 4' | System | 20 Aug 2020 17:36:06 |

US3722338

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:26:23

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-23T13:27:56', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '6d795584-b044-4838-8306-e28ec189eb09' | System | 23 Aug 2020 17:28:14 |
| User entered 'Yes (Y)' | System | 23 Aug 2020 17:28:14 |

US3722338

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:26:23

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-23T13:28:03', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '6d795584-b044-4838-8306-e28ec189eb09' | System | 23 Aug 2020 17:28:14 |
| User entered '97.6' | System | 23 Aug 2020 17:28:14 |

US3722338

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-23T13:28:07', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '6d795584-b044-4838-8306-e28ec189eb09' | System | 23 Aug 2020 17:28:14 |
| User entered 'No (N)' | System | 23 Aug 2020 17:28:14 |

US3722338

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:26:23

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-23T13:28:12', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '6d795584-b044-4838-8306-e28ec189eb09' | System | 23 Aug 2020 17:28:14 |
| User entered '23 Aug 2020 13:28' | System | 23 Aug 2020 17:28:14 |

US3722338

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:26:23

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| User entered '23 Aug 2020 12:00' | System | 20 Aug 2020 17:36:06 |

US3722338

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:26:23

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| User entered '24 Aug 2020 11:59' | System | 20 Aug 2020 17:36:06 |

US3722338

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| Data entry locked. | System | 20 Aug 2020 17:36:06 |
| User entered 'Day 5' | System | 20 Aug 2020 17:36:06 |

US3722338

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:26:23

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-24T14:29:18', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '971ac258-e0d3-432f-97bf-72e95a2fcb07' | System | 24 Aug 2020 18:29:37 |
| User entered 'Yes (Y)' | System | 24 Aug 2020 18:29:37 |

US3722338

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:26:23

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-24T14:29:25', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '971ac258-e0d3-432f-97bf-72e95a2fcb07' | System | 24 Aug 2020 18:29:37 |
| User entered '98.8' | System | 24 Aug 2020 18:29:37 |

US3722338

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-24T14:29:28', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '971ac258-e0d3-432f-97bf-72e95a2fcb07' | System | 24 Aug 2020 18:29:37 |
| User entered 'No (N)' | System | 24 Aug 2020 18:29:37 |

US3722338

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:26:23

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-24T14:29:34', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '971ac258-e0d3-432f-97bf-72e95a2fcb07' | System | 24 Aug 2020 18:29:37 |
| User entered '24 Aug 2020 14:29' | System | 24 Aug 2020 18:29:37 |

US3722338

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:26:23

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| User entered '24 Aug 2020 12:00' | System | 20 Aug 2020 17:36:06 |

US3722338

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:26:23

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| User entered '25 Aug 2020 11:59' | System | 20 Aug 2020 17:36:06 |

US3722338

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| Data entry locked. | System | 20 Aug 2020 17:36:06 |
| User entered 'Day 6' | System | 20 Aug 2020 17:36:06 |

US3722338

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:26:23

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-25T13:12:00', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '55feef4b-4e85-45bf-8a68-76c357a90307' | System | 25 Aug 2020 17:12:19 |
| User entered 'Yes (Y)' | System | 25 Aug 2020 17:12:19 |

US3722338

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:26:23

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-25T13:12:07', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '55feef4b-4e85-45bf-8a68-76c357a90307' | System | 25 Aug 2020 17:12:19 |
| User entered '96.3' | System | 25 Aug 2020 17:12:19 |

US3722338

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-25T13:12:10', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '55feef4b-4e85-45bf-8a68-76c357a90307' | System | 25 Aug 2020 17:12:19 |
| User entered 'No (N)' | System | 25 Aug 2020 17:12:19 |

US3722338

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:26:23

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-25T13:12:14', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '55feef4b-4e85-45bf-8a68-76c357a90307' | System | 25 Aug 2020 17:12:19 |
| User entered '25 Aug 2020 13:12' | System | 25 Aug 2020 17:12:19 |

US3722338

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:26:23

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| User entered '25 Aug 2020 12:00' | System | 20 Aug 2020 17:36:06 |

US3722338

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:26:23

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| User entered '26 Aug 2020 11:59' | System | 20 Aug 2020 17:36:06 |

US3722338

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| Data entry locked. | System | 20 Aug 2020 17:36:06 |
| User entered 'Day 7' | System | 20 Aug 2020 17:36:06 |

US3722338

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:26:23

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-26T13:06:14', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '6a59efef-db31-482f-8aa6-d6b4be6d6530' | System | 26 Aug 2020 17:06:36 |
| User entered 'Yes (Y)' | System | 26 Aug 2020 17:06:36 |

US3722338

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:26:23

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-26T13:06:22', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '6a59efef-db31-482f-8aa6-d6b4be6d6530' | System | 26 Aug 2020 17:06:36 |
| User entered '97.6' | System | 26 Aug 2020 17:06:36 |

US3722338

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-26T13:06:26', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '6a59efef-db31-482f-8aa6-d6b4be6d6530' | System | 26 Aug 2020 17:06:36 |
| User entered 'No (N)' | System | 26 Aug 2020 17:06:36 |

US3722338

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:26:23

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-26T13:06:30', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '6a59efef-db31-482f-8aa6-d6b4be6d6530' | System | 26 Aug 2020 17:06:36 |
| User entered '26 Aug 2020 13:06' | System | 26 Aug 2020 17:06:36 |

US3722338

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:26:23

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| User entered '26 Aug 2020 12:00' | System | 20 Aug 2020 17:36:06 |

US3722338

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:26:23

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| User entered '27 Aug 2020 11:59' | System | 20 Aug 2020 17:36:06 |

US3722338

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| Data entry locked. | System | 20 Aug 2020 17:36:06 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 20 Aug 2020 17:36:06 |

US3722338

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:26:23

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 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-20T13:37:58', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '404a8392-2d8e-45e8-980e-b8feb817e95e' | System | 20 Aug 2020 17:38:29 |
| User entered 'None (1)' | System | 20 Aug 2020 17:38:29 |

US3722338

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:26:23

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-20T13:38:07', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '404a8392-2d8e-45e8-980e-b8feb817e95e' | System | 20 Aug 2020 17:38:29 |
| User entered 'No (N)' | System | 20 Aug 2020 17:38:29 |

US3722338

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-20T13:38:11', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '404a8392-2d8e-45e8-980e-b8feb817e95e' | System | 20 Aug 2020 17:38:29 |
| User entered 'No (N)' | System | 20 Aug 2020 17:38:29 |

US3722338

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:26:23

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 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-20T13:38:17', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '404a8392-2d8e-45e8-980e-b8feb817e95e' | System | 20 Aug 2020 17:38:29 |
| User entered 'None (1)' | System | 20 Aug 2020 17:38:29 |

US3722338

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:26:23

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-20T13:38:22', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '404a8392-2d8e-45e8-980e-b8feb817e95e' | System | 20 Aug 2020 17:38:29 |
| User entered '20 Aug 2020 13:38' | System | 20 Aug 2020 17:38:29 |

US3722338

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:26:23

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| User entered '20 Aug 2020 13:25' | System | 20 Aug 2020 17:36:06 |

US3722338

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:26:23

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| User entered '20 Aug 2020 15:55' | System | 20 Aug 2020 17:36:06 |

US3722338

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| Data entry locked. | System | 20 Aug 2020 17:36:06 |
| User entered 'Day 1, after vaccination (at home)' | System | 20 Aug 2020 17:36:06 |

US3722338

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:26:23

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 02:35:10 |
| | | |

US3722338

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| | | |

US3722338

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:26:23

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

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| | | |

US3722338

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| | | |

US3722338

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:26:23

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

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| | | |

US3722338

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:26:23

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 02:35:10 |
| | | |

US3722338

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:26:23

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| | | |

US3722338

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:26:23

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| User entered '20 Aug 2020 16:50' | System | 20 Aug 2020 17:36:06 |

US3722338

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:26:23

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| User entered '21 Aug 2020 11:59' | System | 20 Aug 2020 17:36:06 |

US3722338

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| Data entry locked. | System | 20 Aug 2020 17:36:06 |
| User entered 'Day 2' | System | 20 Aug 2020 17:36:06 |

US3722338

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:26:23

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 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-21T14:01:59', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '57bd6560-b737-4ddf-becb-1fda51ae5683' | System | 21 Aug 2020 18:02:28 |
| User entered 'None (1)' | System | 21 Aug 2020 18:02:28 |

US3722338

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:26:23

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-21T14:02:03', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '57bd6560-b737-4ddf-becb-1fda51ae5683' | System | 21 Aug 2020 18:02:28 |
| User entered 'No (N)' | System | 21 Aug 2020 18:02:28 |

US3722338

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-21T14:02:07', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '57bd6560-b737-4ddf-becb-1fda51ae5683' | System | 21 Aug 2020 18:02:28 |
| User entered 'No (N)' | System | 21 Aug 2020 18:02:28 |

US3722338

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:26:23

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 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-21T14:02:14', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '57bd6560-b737-4ddf-becb-1fda51ae5683' | System | 21 Aug 2020 18:02:28 |
| User entered 'None (1)' | System | 21 Aug 2020 18:02:28 |

US3722338

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:26:23

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-21T14:02:22', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '57bd6560-b737-4ddf-becb-1fda51ae5683' | System | 21 Aug 2020 18:02:28 |
| User entered '21 Aug 2020 14:02' | System | 21 Aug 2020 18:02:28 |

US3722338

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:26:23

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| User entered '21 Aug 2020 12:00' | System | 20 Aug 2020 17:36:06 |

US3722338

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:26:23

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| User entered '22 Aug 2020 11:59' | System | 20 Aug 2020 17:36:06 |

US3722338

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| Data entry locked. | System | 20 Aug 2020 17:36:06 |
| User entered 'Day 3' | System | 20 Aug 2020 17:36:06 |

US3722338

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:26:23

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 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-22T20:45:12', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'bee3fa49-0a6b-4b2f-aeb0-ee112d937fb2' | System | 23 Aug 2020 00:45:31 |
| User entered 'None (1)' | System | 23 Aug 2020 00:45:31 |

US3722338

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:26:23

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-22T20:45:16', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'bee3fa49-0a6b-4b2f-aeb0-ee112d937fb2' | System | 23 Aug 2020 00:45:31 |
| User entered 'No (N)' | System | 23 Aug 2020 00:45:31 |

US3722338

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-22T20:45:20', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'bee3fa49-0a6b-4b2f-aeb0-ee112d937fb2' | System | 23 Aug 2020 00:45:31 |
| User entered 'No (N)' | System | 23 Aug 2020 00:45:31 |

US3722338

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:26:23

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 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-22T20:45:24', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'bee3fa49-0a6b-4b2f-aeb0-ee112d937fb2' | System | 23 Aug 2020 00:45:31 |
| User entered 'None (1)' | System | 23 Aug 2020 00:45:31 |

US3722338

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:26:23

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-22T20:45:29', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'bee3fa49-0a6b-4b2f-aeb0-ee112d937fb2' | System | 23 Aug 2020 00:45:31 |
| User entered '22 Aug 2020 20:45' | System | 23 Aug 2020 00:45:31 |

US3722338

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:26:23

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| User entered '22 Aug 2020 12:00' | System | 20 Aug 2020 17:36:06 |

US3722338

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:26:23

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| User entered '23 Aug 2020 11:59' | System | 20 Aug 2020 17:36:06 |

US3722338

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| Data entry locked. | System | 20 Aug 2020 17:36:06 |
| User entered 'Day 4' | System | 20 Aug 2020 17:36:06 |

US3722338

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:26:23

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 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-23T13:28:18', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '42439c8d-b7dd-4a61-a79d-548dfbedf134' | System | 23 Aug 2020 17:28:37 |
| User entered 'None (1)' | System | 23 Aug 2020 17:28:37 |

US3722338

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:26:23

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-23T13:28:22', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '42439c8d-b7dd-4a61-a79d-548dfbedf134' | System | 23 Aug 2020 17:28:37 |
| User entered 'No (N)' | System | 23 Aug 2020 17:28:37 |

US3722338

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-23T13:28:25', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '42439c8d-b7dd-4a61-a79d-548dfbedf134' | System | 23 Aug 2020 17:28:37 |
| User entered 'No (N)' | System | 23 Aug 2020 17:28:37 |

US3722338

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:26:23

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 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-23T13:28:29', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '42439c8d-b7dd-4a61-a79d-548dfbedf134' | System | 23 Aug 2020 17:28:37 |
| User entered 'None (1)' | System | 23 Aug 2020 17:28:37 |

US3722338

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:26:23

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-23T13:28:33', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '42439c8d-b7dd-4a61-a79d-548dfbedf134' | System | 23 Aug 2020 17:28:37 |
| User entered '23 Aug 2020 13:28' | System | 23 Aug 2020 17:28:37 |

US3722338

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:26:23

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| User entered '23 Aug 2020 12:00' | System | 20 Aug 2020 17:36:06 |

US3722338

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:26:23

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| User entered '24 Aug 2020 11:59' | System | 20 Aug 2020 17:36:06 |

US3722338

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| Data entry locked. | System | 20 Aug 2020 17:36:06 |
| User entered 'Day 5' | System | 20 Aug 2020 17:36:06 |

US3722338

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:26:23

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 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-24T14:29:41', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'c08a91dc-9524-468e-9162-f3f25b3fb284' | System | 24 Aug 2020 18:30:00 |
| User entered 'None (1)' | System | 24 Aug 2020 18:30:00 |

US3722338

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:26:23

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-24T14:29:45', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'c08a91dc-9524-468e-9162-f3f25b3fb284' | System | 24 Aug 2020 18:30:00 |
| User entered 'No (N)' | System | 24 Aug 2020 18:30:00 |

US3722338

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-24T14:29:48', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'c08a91dc-9524-468e-9162-f3f25b3fb284' | System | 24 Aug 2020 18:30:00 |
| User entered 'No (N)' | System | 24 Aug 2020 18:30:00 |

US3722338

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:26:23

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 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-24T14:29:53', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'c08a91dc-9524-468e-9162-f3f25b3fb284' | System | 24 Aug 2020 18:30:00 |
| User entered 'None (1)' | System | 24 Aug 2020 18:30:00 |

US3722338

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:26:23

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-24T14:29:57', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'c08a91dc-9524-468e-9162-f3f25b3fb284' | System | 24 Aug 2020 18:30:00 |
| User entered '24 Aug 2020 14:29' | System | 24 Aug 2020 18:30:00 |

US3722338

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:26:23

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| User entered '24 Aug 2020 12:00' | System | 20 Aug 2020 17:36:06 |

US3722338

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:26:23

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| User entered '25 Aug 2020 11:59' | System | 20 Aug 2020 17:36:06 |

US3722338

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| Data entry locked. | System | 20 Aug 2020 17:36:06 |
| User entered 'Day 6' | System | 20 Aug 2020 17:36:06 |

US3722338

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:26:23

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 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-25T13:12:21', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'e8c0c6a2-708a-437f-8e61-3565ad1906e9' | System | 25 Aug 2020 17:12:41 |
| User entered 'None (1)' | System | 25 Aug 2020 17:12:41 |

US3722338

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:26:23

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-25T13:12:25', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'e8c0c6a2-708a-437f-8e61-3565ad1906e9' | System | 25 Aug 2020 17:12:41 |
| User entered 'No (N)' | System | 25 Aug 2020 17:12:41 |

US3722338

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-25T13:12:28', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'e8c0c6a2-708a-437f-8e61-3565ad1906e9' | System | 25 Aug 2020 17:12:41 |
| User entered 'No (N)' | System | 25 Aug 2020 17:12:41 |

US3722338

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:26:23

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 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-25T13:12:33', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'e8c0c6a2-708a-437f-8e61-3565ad1906e9' | System | 25 Aug 2020 17:12:41 |
| User entered 'None (1)' | System | 25 Aug 2020 17:12:41 |

US3722338

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:26:23

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-25T13:12:36', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'e8c0c6a2-708a-437f-8e61-3565ad1906e9' | System | 25 Aug 2020 17:12:41 |
| User entered '25 Aug 2020 13:12' | System | 25 Aug 2020 17:12:41 |

US3722338

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:26:23

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| User entered '25 Aug 2020 12:00' | System | 20 Aug 2020 17:36:06 |

US3722338

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:26:23

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| User entered '26 Aug 2020 11:59' | System | 20 Aug 2020 17:36:06 |

US3722338

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| Data entry locked. | System | 20 Aug 2020 17:36:06 |
| User entered 'Day 7' | System | 20 Aug 2020 17:36:06 |

US3722338

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:26:23

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 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-26T13:06:40', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'c5ce9ccb-3272-4550-8fde-f95b41c7f3fa' | System | 26 Aug 2020 17:06:55 |
| User entered 'None (1)' | System | 26 Aug 2020 17:06:55 |

US3722338

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-26T13:06:44', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'c5ce9ccb-3272-4550-8fde-f95b41c7f3fa' | System | 26 Aug 2020 17:06:55 |
| User entered 'No (N)' | System | 26 Aug 2020 17:06:55 |

US3722338

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-26T13:06:47', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'c5ce9ccb-3272-4550-8fde-f95b41c7f3fa' | System | 26 Aug 2020 17:06:55 |
| User entered 'No (N)' | System | 26 Aug 2020 17:06:55 |

US3722338

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:26:23

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 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-26T13:06:51', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'c5ce9ccb-3272-4550-8fde-f95b41c7f3fa' | System | 26 Aug 2020 17:06:55 |
| User entered 'None (1)' | System | 26 Aug 2020 17:06:55 |

US3722338

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:26:23

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-26T13:06:54', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'c5ce9ccb-3272-4550-8fde-f95b41c7f3fa' | System | 26 Aug 2020 17:06:55 |
| User entered '26 Aug 2020 13:06' | System | 26 Aug 2020 17:06:55 |

US3722338

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:26:23

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| User entered '26 Aug 2020 12:00' | System | 20 Aug 2020 17:36:06 |

US3722338

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:26:23

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| User entered '27 Aug 2020 11:59' | System | 20 Aug 2020 17:36:06 |

US3722338

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| Data entry locked. | System | 20 Aug 2020 17:36:06 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 20 Aug 2020 17:36:06 |

US3722338

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:26:23

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-20T13:38:29', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '76d74ef9-aacb-449c-a807-4873e057528f' User entered 'None (0)' | System | 20 Aug 2020 17:39:10 |
| | System | 20 Aug 2020 17:39:10 |

US3722338

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:26:23

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-20T13:38:39', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '76d74ef9-aacb-449c-a807-4873e057528f' User entered 'None (0)' | System | 20 Aug 2020 17:39:10 |
| | System | 20 Aug 2020 17:39:10 |

US3722338

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:26:23

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-20T13:38:42', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '76d74ef9-aacb-449c-a807-4873e057528f' User entered 'None (0)' | System | 20 Aug 2020 17:39:10 |
| | System | 20 Aug 2020 17:39:10 |

US3722338

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:26:23

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-20T13:38:45', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '76d74ef9-aacb-449c-a807-4873e057528f' User entered 'None (0)' | System | 20 Aug 2020 17:39:10 |
| | System | 20 Aug 2020 17:39:10 |

US3722338

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:26:23

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-20T13:38:49', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '76d74ef9-aacb-449c-a807-4873e057528f' User entered 'None (0)' | System | 20 Aug 2020 17:39:10 |
| | System | 20 Aug 2020 17:39:10 |

US3722338

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:26:23

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-20T13:38:52', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '76d74ef9-aacb-449c-a807-4873e057528f' User entered 'None (0)' | System | 20 Aug 2020 17:39:10 |
| | System | 20 Aug 2020 17:39:10 |

US3722338

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:26:23

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 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-20T13:38:58', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '76d74ef9-aacb-449c-a807-4873e057528f' | System | 20 Aug 2020 17:39:10 |
| User entered 'No (N)' | System | 20 Aug 2020 17:39:10 |

US3722338

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:26:23

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-20T13:39:03', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '76d74ef9-aacb-449c-a807-4873e057528f' User entered '20 Aug 2020 13:39' | System | 20 Aug 2020 17:39:10 |
| | System | 20 Aug 2020 17:39:10 |

US3722338

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:26:23

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| User entered '20 Aug 2020 13:25' | System | 20 Aug 2020 17:36:06 |

US3722338

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:26:23

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| User entered '20 Aug 2020 15:55' | System | 20 Aug 2020 17:36:06 |

US3722338

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| Data entry locked. | System | 20 Aug 2020 17:36:06 |
| User entered 'Day 1, after vaccination (at home)' | System | 20 Aug 2020 17:36:06 |

US3722338

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:26:23

HEADACHE

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| | | |

US3722338

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:26:23

FATIGUE

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| | | |

US3722338

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:26:23

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| | | |

US3722338

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:26:23

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| | | |

US3722338

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:26:23

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| | | |

US3722338

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:26:23

CHILLS

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| | | |

US3722338

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:26:23

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 02:35:10 |
| | | |

US3722338

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:26:23

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| | | |

US3722338

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:26:23

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| User entered '20 Aug 2020 16:50' | System | 20 Aug 2020 17:36:06 |

US3722338

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:26:23

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| User entered '21 Aug 2020 11:59' | System | 20 Aug 2020 17:36:06 |

US3722338

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| Data entry locked. | System | 20 Aug 2020 17:36:06 |
| User entered 'Day 2' | System | 20 Aug 2020 17:36:06 |

US3722338

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:26:23

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-21T14:02:31', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '8a28ff08-9a1e-4431-925b-454f082928b3' | System | 21 Aug 2020 18:02:59 |
| User entered 'None (0)' | System | 21 Aug 2020 18:02:59 |

US3722338

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:26:23

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-21T14:02:34', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '8a28ff08-9a1e-4431-925b-454f082928b3' | System | 21 Aug 2020 18:02:59 |
| User entered 'None (0)' | System | 21 Aug 2020 18:02:59 |

US3722338

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:26:23

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-21T14:02:38', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '8a28ff08-9a1e-4431-925b-454f082928b3' | System | 21 Aug 2020 18:02:59 |
| User entered 'None (0)' | System | 21 Aug 2020 18:02:59 |

US3722338

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:26:23

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-21T14:02:41', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '8a28ff08-9a1e-4431-925b-454f082928b3' | System | 21 Aug 2020 18:02:59 |
| User entered 'None (0)' | System | 21 Aug 2020 18:02:59 |

US3722338

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:26:23

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-21T14:02:45', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '8a28ff08-9a1e-4431-925b-454f082928b3' | System | 21 Aug 2020 18:02:59 |
| User entered 'None (0)' | System | 21 Aug 2020 18:02:59 |

US3722338

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:26:23

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-21T14:02:47', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '8a28ff08-9a1e-4431-925b-454f082928b3' | System | 21 Aug 2020 18:02:59 |
| User entered 'None (0)' | System | 21 Aug 2020 18:02:59 |

US3722338

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:26:23

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 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-21T14:02:52', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '8a28ff08-9a1e-4431-925b-454f082928b3' | System | 21 Aug 2020 18:02:59 |
| User entered 'No (N)' | System | 21 Aug 2020 18:02:59 |

US3722338

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:26:23

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-21T14:02:56', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '8a28ff08-9a1e-4431-925b-454f082928b3' | System | 21 Aug 2020 18:02:59 |
| User entered '21 Aug 2020 14:02' | System | 21 Aug 2020 18:02:59 |

US3722338

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:26:23

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| User entered '21 Aug 2020 12:00' | System | 20 Aug 2020 17:36:06 |

US3722338

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:26:23

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| User entered '22 Aug 2020 11:59' | System | 20 Aug 2020 17:36:06 |

US3722338

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| Data entry locked. | System | 20 Aug 2020 17:36:06 |
| User entered 'Day 3' | System | 20 Aug 2020 17:36:06 |

US3722338

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:26:23

HEADACHE

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-22T20:45:36', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'bfd2992-fa5f-4e63-b82e-6a78da58563d' | System | 23 Aug 2020 00:46:04 |
| User entered 'None (0)' | System | 23 Aug 2020 00:46:04 |

US3722338

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:26:23

FATIGUE

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-22T20:45:39', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'bfd2992-fa5f-4e63-b82e-6a78da58563d' | System | 23 Aug 2020 00:46:04 |
| User entered 'None (0)' | System | 23 Aug 2020 00:46:04 |

US3722338

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:26:23

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-22T20:45:43', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'bfd2992-fa5f-4e63-b82e-6a78da58563d' | System | 23 Aug 2020 00:46:04 |
| User entered 'None (0)' | System | 23 Aug 2020 00:46:04 |

US3722338

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:26:23

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-22T20:45:47', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'bfd2992-fa5f-4e63-b82e-6a78da58563d' | System | 23 Aug 2020 00:46:04 |
| User entered 'None (0)' | System | 23 Aug 2020 00:46:04 |

US3722338

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:26:23

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-22T20:45:50', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'bfd2992-fa5f-4e63-b82e-6a78da58563d' | System | 23 Aug 2020 00:46:04 |
| User entered 'None (0)' | System | 23 Aug 2020 00:46:04 |

US3722338

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:26:23

CHILLS

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-22T20:45:54', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'bfd2992-fa5f-4e63-b82e-6a78da58563d' | System | 23 Aug 2020 00:46:04 |
| User entered 'None (0)' | System | 23 Aug 2020 00:46:04 |

US3722338

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:26:23

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 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-22T20:45:59', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'bfd2992-fa5f-4e63-b82e-6a78da58563d' | System | 23 Aug 2020 00:46:04 |
| User entered 'No (N)' | System | 23 Aug 2020 00:46:04 |

US3722338

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:26:23

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-22T20:46:02', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'bfdf2992-fa5f-4e63-b82e-6a78da58563d' | System | 23 Aug 2020 00:46:04 |
| User entered '22 Aug 2020 20:46' | System | 23 Aug 2020 00:46:04 |

US3722338

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:26:23

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| User entered '22 Aug 2020 12:00' | System | 20 Aug 2020 17:36:06 |

US3722338

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:26:23

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| User entered '23 Aug 2020 11:59' | System | 20 Aug 2020 17:36:06 |

US3722338

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| Data entry locked. | System | 20 Aug 2020 17:36:06 |
| User entered 'Day 4' | System | 20 Aug 2020 17:36:06 |

US3722338

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:26:23

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-23T13:28:40', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '3b350c04-65ac-4a47-aae2-07d71d656c52' | System | 23 Aug 2020 17:29:08 |
| User entered 'None (0)' | System | 23 Aug 2020 17:29:08 |

US3722338

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:26:23

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-23T13:28:43', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '3b350c04-65ac-4a47-aae2-07d71d656c52' | System | 23 Aug 2020 17:29:08 |
| User entered 'None (0)' | System | 23 Aug 2020 17:29:08 |

US3722338

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:26:23

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-23T13:28:46', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '3b350c04-65ac-4a47-aae2-07d71d656c52' | System | 23 Aug 2020 17:29:08 |
| User entered 'None (0)' | System | 23 Aug 2020 17:29:08 |

US3722338

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:26:23

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-23T13:28:49', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '3b350c04-65ac-4a47-aae2-07d71d656c52' | System | 23 Aug 2020 17:29:08 |
| User entered 'None (0)' | System | 23 Aug 2020 17:29:08 |

US3722338

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:26:23

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-23T13:28:52', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '3b350c04-65ac-4a47-aae2-07d71d656c52' | System | 23 Aug 2020 17:29:08 |
| User entered 'None (0)' | System | 23 Aug 2020 17:29:08 |

US3722338

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:26:23

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-23T13:28:55', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '3b350c04-65ac-4a47-aae2-07d71d656c52' | System | 23 Aug 2020 17:29:08 |
| User entered 'None (0)' | System | 23 Aug 2020 17:29:08 |

US3722338

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:26:23

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 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-23T13:29:02', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '3b350c04-65ac-4a47-aae2-07d71d656c52' | System | 23 Aug 2020 17:29:08 |
| User entered 'No (N)' | System | 23 Aug 2020 17:29:08 |

US3722338

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:26:23

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-23T13:29:05', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '3b350c04-65ac-4a47-aae2-07d71d656c52' | System | 23 Aug 2020 17:29:08 |
| User entered '23 Aug 2020 13:29' | System | 23 Aug 2020 17:29:08 |

US3722338

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:26:23

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| User entered '23 Aug 2020 12:00' | System | 20 Aug 2020 17:36:06 |

US3722338

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:26:23

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| User entered '24 Aug 2020 11:59' | System | 20 Aug 2020 17:36:06 |

US3722338

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| Data entry locked. | System | 20 Aug 2020 17:36:06 |
| User entered 'Day 5' | System | 20 Aug 2020 17:36:06 |

US3722338

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:26:23

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-24T14:30:03', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'c4653c36-dd2f-428d-95b2-0732863dbb2d' | System | 24 Aug 2020 18:30:31 |
| User entered 'None (0)' | System | 24 Aug 2020 18:30:31 |

US3722338

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:26:23

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-24T14:30:06', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'c4653c36-dd2f-428d-95b2-0732863dbb2d' | System | 24 Aug 2020 18:30:31 |
| User entered 'None (0)' | System | 24 Aug 2020 18:30:31 |

US3722338

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:26:23

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-24T14:30:09', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'c4653c36-dd2f-428d-95b2-0732863dbb2d' | System | 24 Aug 2020 18:30:31 |
| User entered 'None (0)' | System | 24 Aug 2020 18:30:31 |

US3722338

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:26:23

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-24T14:30:12', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'c4653c36-dd2f-428d-95b2-0732863dbb2d' | System | 24 Aug 2020 18:30:31 |
| User entered 'None (0)' | System | 24 Aug 2020 18:30:31 |

US3722338

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:26:23

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-24T14:30:15', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'c4653c36-dd2f-428d-95b2-0732863dbb2d' | System | 24 Aug 2020 18:30:31 |
| User entered 'None (0)' | System | 24 Aug 2020 18:30:31 |

US3722338

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:26:23

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-24T14:30:17', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'c4653c36-dd2f-428d-95b2-0732863dbb2d' | System | 24 Aug 2020 18:30:31 |
| User entered 'None (0)' | System | 24 Aug 2020 18:30:31 |

US3722338

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:26:23

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 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-24T14:30:24', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'c4653c36-dd2f-428d-95b2-0732863dbb2d' | System | 24 Aug 2020 18:30:31 |
| User entered 'No (N)' | System | 24 Aug 2020 18:30:31 |

US3722338

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:26:23

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-24T14:30:27', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'c4653c36-dd2f-428d-95b2-0732863dbb2d' | System | 24 Aug 2020 18:30:31 |
| User entered '24 Aug 2020 14:30' | System | 24 Aug 2020 18:30:31 |

US3722338

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:26:23

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| User entered '24 Aug 2020 12:00' | System | 20 Aug 2020 17:36:06 |

US3722338

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:26:23

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| User entered '25 Aug 2020 11:59' | System | 20 Aug 2020 17:36:06 |

US3722338

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| Data entry locked. | System | 20 Aug 2020 17:36:06 |
| User entered 'Day 6' | System | 20 Aug 2020 17:36:06 |

US3722338

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:26:23

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-25T13:12:43', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '5154f968-8773-426f-bf4f-702da0720f94' | System | 25 Aug 2020 17:13:09 |
| User entered 'None (0)' | System | 25 Aug 2020 17:13:09 |

US3722338

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:26:23

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-25T13:12:46', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '5154f968-8773-426f-bf4f-702da0720f94' | System | 25 Aug 2020 17:13:09 |
| User entered 'None (0)' | System | 25 Aug 2020 17:13:09 |

US3722338

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:26:23

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-25T13:12:49', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '5154f968-8773-426f-bf4f-702da0720f94' | System | 25 Aug 2020 17:13:09 |
| User entered 'None (0)' | System | 25 Aug 2020 17:13:09 |

US3722338

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:26:23

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-25T13:12:52', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '5154f968-8773-426f-bf4f-702da0720f94' | System | 25 Aug 2020 17:13:09 |
| User entered 'None (0)' | System | 25 Aug 2020 17:13:09 |

US3722338

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:26:23

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-25T13:12:55', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '5154f968-8773-426f-bf4f-702da0720f94' | System | 25 Aug 2020 17:13:09 |
| User entered 'None (0)' | System | 25 Aug 2020 17:13:09 |

US3722338

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:26:23

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-25T13:12:58', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '5154f968-8773-426f-bf4f-702da0720f94' | System | 25 Aug 2020 17:13:09 |
| User entered 'None (0)' | System | 25 Aug 2020 17:13:09 |

US3722338

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:26:23

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 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-25T13:13:02', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '5154f968-8773-426f-bf4f-702da0720f94' | System | 25 Aug 2020 17:13:09 |
| User entered 'No (N)' | System | 25 Aug 2020 17:13:09 |

US3722338

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:26:23

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-25T13:13:06', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '5154f968-8773-426f-bf4f-702da0720f94' | System | 25 Aug 2020 17:13:09 |
| User entered '25 Aug 2020 13:13' | System | 25 Aug 2020 17:13:09 |

US3722338

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:26:23

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| User entered '25 Aug 2020 12:00' | System | 20 Aug 2020 17:36:06 |

US3722338

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:26:23

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| User entered '26 Aug 2020 11:59' | System | 20 Aug 2020 17:36:06 |

US3722338

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| Data entry locked. | System | 20 Aug 2020 17:36:06 |
| User entered 'Day 7' | System | 20 Aug 2020 17:36:06 |

US3722338

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:26:23

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-26T13:07:00', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'beb543b5-94f9-48be-bf42-c21e925f7c6c' | System | 26 Aug 2020 17:07:42 |
| User entered 'None (0)' | System | 26 Aug 2020 17:07:42 |

US3722338

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:26:23

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-26T13:07:02', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'beb543b5-94f9-48be-bf42-c21e925f7c6c' | System | 26 Aug 2020 17:07:42 |
| User entered 'None (0)' | System | 26 Aug 2020 17:07:42 |

US3722338

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:26:23

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-26T13:07:11', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'beb543b5-94f9-48be-bf42-c21e925f7c6c' | System | 26 Aug 2020 17:07:42 |
| User entered 'None (0)' | System | 26 Aug 2020 17:07:42 |

US3722338

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:26:23

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-26T13:07:15', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'beb543b5-94f9-48be-bf42-c21e925f7c6c' | System | 26 Aug 2020 17:07:42 |
| User entered 'None (0)' | System | 26 Aug 2020 17:07:42 |

US3722338

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:26:23

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-26T13:07:19', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'beb543b5-94f9-48be-bf42-c21e925f7c6c' | System | 26 Aug 2020 17:07:42 |
| User entered 'None (0)' | System | 26 Aug 2020 17:07:42 |

US3722338

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:26:23

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-26T13:07:22', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'beb543b5-94f9-48be-bf42-c21e925f7c6c' | System | 26 Aug 2020 17:07:42 |
| User entered 'None (0)' | System | 26 Aug 2020 17:07:42 |

US3722338

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:26:23

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 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-26T13:07:34', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'beb543b5-94f9-48be-bf42-c21e925f7c6c' | System | 26 Aug 2020 17:07:42 |
| User entered 'No (N)' | System | 26 Aug 2020 17:07:42 |

US3722338

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:26:23

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-08-26T13:07:38', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'beb543b5-94f9-48be-bf42-c21e925f7c6c' | System | 26 Aug 2020 17:07:42 |
| User entered '26 Aug 2020 13:07' | System | 26 Aug 2020 17:07:42 |

US3722338

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:26:23

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| User entered '26 Aug 2020 12:00' | System | 20 Aug 2020 17:36:06 |

US3722338

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:26:23

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| User entered '27 Aug 2020 11:59' | System | 20 Aug 2020 17:36:06 |

US3722338

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:26:23

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:44:34 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered 'Yes (Y)' | Amy Ford (b) (4) | 31 Aug 2020 01:04:39 |

US3722338

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:26:23

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:44:34 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered '30 Aug 2020' | Amy Ford (b) (4) | 31 Aug 2020 01:04:39 |

US3722338

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:26:23

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:44:34 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered 'Contact Made (CONTACT MADE)' | Amy Ford (b) (4) | 31 Aug 2020 01:04:39 |

US3722338

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:26:23

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:44:34 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered empty. | Amy Ford (b) (4) | 31 Aug 2020 01:04:39 |

US3722338

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:26:23

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:44:34 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered 'Yes (Y)' | Amy Ford (b) (4) | 31 Aug 2020 01:04:44 |

US3722338

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:26:23

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:44:34 |
| User entered 'I' | System | 31 Aug 2020 01:04:44 |

US3722338

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:26:23

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:44:34 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered 'Yes (Y)' | Kayla Peay (b) (4) | 08 Sep 2020 12:55:42 |

US3722338

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:26:23

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:44:34 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered '03 Sep 2020' reason for change: Data Entry Error | (b) (4) | |
| | Sara Poff (b) (4) | 10 Nov 2020 22:20:32 |
| User entered '3 Sep 2020' | (b) (4) | |
| | Kayla Peay (b) (4) | 08 Sep 2020 12:55:42 |
| | (b) (4) | |

US3722338

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:26:23

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:44:34 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered 'Contact Made (CONTACT MADE)' | Kayla Peay (b) (4) | 08 Sep 2020 12:55:42 |

US3722338

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:26:23

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:44:34 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered empty. | Kayla Peay (b) (4) | 08 Sep 2020 12:55:42 |

US3722338

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:26:23

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:44:34 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered 'Yes (Y)' | Kayla Peay (b) (4) | 08 Sep 2020 12:55:46 |

US3722338

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:26:23

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:44:34 |
| User entered 'I' | System | 08 Sep 2020 12:55:46 |

US3722338

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:26:23

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered 'Yes (Y)' | Kayla Peay (b) (4) | 14 Sep 2020 17:14:56 |

US3722338

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:26:23

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered '11 Sep 2020' reason for change: Data Entry Error | Kayla Peay (b) (4) | 25 Sep 2020 18:39:45 |
| User entered '10 Sep 2020' | Kayla Peay (b) (4) | 14 Sep 2020 17:14:56 |

US3722338

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:26:23

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered 'Contact Made (CONTACT MADE)' | Kayla Peay (b) (4) | 14 Sep 2020 17:14:56 |

US3722338

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:26:23

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered empty. | Kayla Peay (b) (4) | 14 Sep 2020 17:14:56 |

US3722338

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:26:23

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered 'Yes (Y)' | Kayla Peay (b) (4) | 14 Sep 2020 17:14:59 |

US3722338

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:26:23

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User entered 'I' | System | 14 Sep 2020 17:14:59 |

US3722338

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:26:23

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered 'Yes (Y)' | Sara Poff (b) (4) | 17 Sep 2020 14:42:23 |

US3722338

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered '17 Sep 2020' | Sara Poff (b) (4) | 17 Sep 2020 14:42:23 |

US3722338

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|--------------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered 'Clinic (Clinic)' | Sara Poff (b) (4) | 17 Sep 2020 14:42:23 |

US3722338

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:26:23

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User entered 'VISIT2' | System | 17 Sep 2020 14:42:23 |

US3722338

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:26:23

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User accepted default value 'Pre-Dose (PREDOSE)' | Kayla Peay (b) (4) (b) (4) | 17 Sep 2020 17:53:16 |

US3722338

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:26:23

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered 'Yes (Y)' | Kayla Peay (b) (4) | 17 Sep 2020 17:53:16 |

US3722338

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:26:23

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered '17 Sep 2020' | Kayla Peay (b) (4) | 17 Sep 2020 17:53:16 |

US3722338

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered '09:15' | Kayla Peay (b) (4) | 17 Sep 2020 17:53:16 |

US3722338

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User entered '17 Sep 2020 09:15' | System | 17 Sep 2020 17:53:16 |

US3722338

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:26:23

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered '98' F | Kayla Peay (b) (4) | 17 Sep 2020 17:53:16 |

US3722338

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:26:23

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered 'Oral (Oral)' | Kayla Peay (b) (4) | 17 Sep 2020 17:53:16 |

US3722338

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:26:23

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered empty. | Kayla Peay (b) (4) | 17 Sep 2020 17:53:16 |

US3722338

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:26:23

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered '73' | Kayla Peay (b) (4) | 17 Sep 2020 17:53:16 |

US3722338

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:26:23

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User entered 'bpm' | System | 17 Sep 2020 17:53:16 |

US3722338

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered '16' | Kayla Peay (b) (4) | 17 Sep 2020 17:53:16 |

US3722338

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:26:23

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User entered 'breaths/min' | System | 17 Sep 2020 17:53:16 |

US3722338

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:26:23

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered '125' | Kayla Peay (b) (4) | 17 Sep 2020 17:53:16 |

US3722338

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:26:23

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User entered 'mmHg' | System | 17 Sep 2020 17:53:16 |

US3722338

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:26:23

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered '61' | Kayla Peay (b) (4) | 17 Sep 2020 17:53:16 |

US3722338

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:26:23

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User entered 'mmHg' | System | 17 Sep 2020 17:53:16 |

US3722338

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:26:23

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User accepted default value 'Post-Dose (POSTDOSE)' | Kayla Peay (b) (4) (b) (4) | 17 Sep 2020 17:53:16 |

US3722338

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:26:23

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered 'Yes (Y)' | Kayla Peay (b) (4) | 17 Sep 2020 17:53:16 |

US3722338

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:26:23

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered '17 Sep 2020' | Kayla Peay (b) (4) | 17 Sep 2020 17:53:16 |

US3722338

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered '11:01' | Kayla Peay (b) (4) | 17 Sep 2020 17:53:16 |

US3722338

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User entered '17 Sep 2020 11:01' | System | 17 Sep 2020 17:53:16 |

US3722338

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:26:23

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered '98' F | Kayla Peay (b) (4) | 17 Sep 2020 17:53:16 |

US3722338

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:26:23

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered 'Oral (Oral)' | Kayla Peay (b) (4) | 17 Sep 2020 17:53:16 |

US3722338

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:26:23

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered empty. | Kayla Peay (b) (4) | 17 Sep 2020 17:53:16 |

US3722338

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:26:23

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered '65' | Kayla Peay (b) (4) | 17 Sep 2020 17:53:16 |

US3722338

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:26:23

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User entered 'bpm' | System | 17 Sep 2020 17:53:16 |

US3722338

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered '18' | Kayla Peay (b) (4) | 17 Sep 2020 17:53:16 |

US3722338

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:26:23

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User entered 'breaths/min' | System | 17 Sep 2020 17:53:16 |

US3722338

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:26:23

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered '127' | Kayla Peay (b) (4) | 17 Sep 2020 17:53:16 |

US3722338

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:26:23

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User entered 'mmHg' | System | 17 Sep 2020 17:53:16 |

US3722338

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:26:23

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered '66' | Kayla Peay (b) (4) | 17 Sep 2020 17:53:16 |

US3722338

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:26:23

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User entered 'mmHg' | System | 17 Sep 2020 17:53:16 |

US3722338

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:26:23

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered 'Yes (Y)' | Kayla Peay (b) (4) | 17 Sep 2020 17:53:24 |

US3722338

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:26:23

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered '17 Sep 2020' | Kayla Peay (b) (4) | 17 Sep 2020 17:53:24 |

US3722338

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:26:23

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered 'Yes (Y)' | Sara Poff (b) (4) | 17 Sep 2020 14:42:51 |

US3722338

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:26:23

[If No, reason not given](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered empty. | Sara Poff (b) (4) | 17 Sep 2020 14:42:51 |

US3722338

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered empty. | Sara Poff (b) (4) | 17 Sep 2020 14:42:51 |

US3722338

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:26:23

[What was the study treatment?](#)

| Audit | User | Time (GMT) |
|-------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User entered 'MRNA-1273 OR PLACEBO' | System | 17 Sep 2020 14:42:51 |

US3722338

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:26:23

What was the treatment date? (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered '17 Sep 2020' | Sara Poff (b) (4) | 17 Sep 2020 14:42:51 |

US3722338

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered '10:31' | Sara Poff (b) (4) | 17 Sep 2020 14:42:51 |

US3722338

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User entered '17 Sep 2020 10:31' | System | 17 Sep 2020 14:42:51 |

US3722338

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|------------------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered 'Left Arm (LEFT ARM)' | Sara Poff (b) (4) | 17 Sep 2020 14:42:51 |

US3722338

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User entered 'ONCE' | System | 17 Sep 2020 14:42:51 |

US3722338

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:26:23

What was the route of administration for the study treatment?

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User entered 'INTRAMUSCULAR' | System | 17 Sep 2020 14:42:51 |

US3722338

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:26:23

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered 'Yes (Y)' | Kayla Peay (b) (4) | 17 Sep 2020 17:53:35 |

US3722338

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:26:23

Collection date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered '17 Sep 2020' | Kayla Peay (b) (4) | 17 Sep 2020 17:53:35 |

US3722338

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:26:23

Collection time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered '10:00' | Kayla Peay (b) (4) | 17 Sep 2020 17:53:35 |

US3722338

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:26:23

Collection date and time (derived)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User entered '17 Sep 2020 10:00' | System | 17 Sep 2020 17:53:35 |

US3722338

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:26:23

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered '17 Sep 2020' | Kayla Peay (b) (4) | 17 Sep 2020 17:53:48 |

US3722338

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:26:23

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | Kayla Peay (b) (4) (b) (4) | 17 Sep 2020 17:53:48 |

US3722338

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:26:23

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered 'Yes (Y)' | Kayla Peay (b) (4) | 17 Sep 2020 17:53:48 |

US3722338

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:26:23

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered '09:57' | Kayla Peay (b) (4) | 17 Sep 2020 17:53:48 |

US3722338

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:26:23

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User entered '17 Sep 2020 09:57' | System | 17 Sep 2020 17:53:48 |

US3722338

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:26:23

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | Kayla Peay (b) (4) (b) (4) | 17 Sep 2020 17:53:48 |

US3722338

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:26:23

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered 'Yes (Y)' | Kayla Peay (b) (4) | 17 Sep 2020 17:53:48 |

US3722338

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:26:23

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered '09:57' | Kayla Peay (b) (4) | 17 Sep 2020 17:53:48 |

US3722338

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:26:23

Collection date and time (derived)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User entered '17 Sep 2020 09:57' | System | 17 Sep 2020 17:53:48 |

US3722338

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:26:23

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered 'Yes (Y)' | Sara Poff (b) (4) | 17 Sep 2020 14:42:59 |

US3722338

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:26:23

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User entered 'I' | System | 17 Sep 2020 14:42:59 |

US3722338

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| Data entry locked. | System | 17 Sep 2020 14:42:51 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 17 Sep 2020 14:42:51 |

US3722338

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:26:23

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-17T11:01:19', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '294b381b-8418-41c9-9d77-c467c2994a85' | System | 17 Sep 2020 15:01:57 |
| User entered 'Yes (Y)' | System | 17 Sep 2020 15:01:57 |

US3722338

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:26:23

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-17T11:01:26', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '294b381b-8418-41c9-9d77-c467c2994a85' | System | 17 Sep 2020 15:01:57 |
| User entered '98.0' | System | 17 Sep 2020 15:01:57 |

US3722338

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-17T11:01:30', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '294b381b-8418-41c9-9d77-c467c2994a85' | System | 17 Sep 2020 15:01:57 |
| User entered 'No (N)' | System | 17 Sep 2020 15:01:57 |

US3722338

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:26:23

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-17T11:01:46', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '294b381b-8418-41c9-9d77-c467c2994a85' | System | 17 Sep 2020 15:01:57 |
| User entered '17 Sep 2020 11:01' | System | 17 Sep 2020 15:01:57 |

US3722338

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:26:23

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| User entered '17 Sep 2020 10:51' | System | 17 Sep 2020 14:42:51 |

US3722338

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:26:23

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| User entered '17 Sep 2020 13:21' | System | 17 Sep 2020 14:42:51 |

US3722338

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| Data entry locked. | System | 17 Sep 2020 14:42:51 |
| User entered 'Day 1, after vaccination (at home)' | System | 17 Sep 2020 14:42:51 |

US3722338

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:26:23

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-17T18:13:45', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'da06df0f-03ff-44a4-b92f-554c3a0444a4' | System | 17 Sep 2020 22:14:07 |
| User entered 'Yes (Y)' | System | 17 Sep 2020 22:14:07 |

US3722338

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:26:23

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-17T18:13:52', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'da06df0f-03ff-44a4-b92f-554c3a0444a4' | System | 17 Sep 2020 22:14:07 |
| User entered '98.1' | System | 17 Sep 2020 22:14:07 |

US3722338

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-17T18:13:56', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'da06df0f-03ff-44a4-b92f-554c3a0444a4' | System | 17 Sep 2020 22:14:07 |
| User entered 'No (N)' | System | 17 Sep 2020 22:14:07 |

US3722338

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:26:23

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-17T18:14:00', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'da06df0f-03ff-44a4-b92f-554c3a0444a4' | System | 17 Sep 2020 22:14:07 |
| User entered '17 Sep 2020 18:14' | System | 17 Sep 2020 22:14:07 |

US3722338

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:26:23

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| User entered '17 Sep 2020 14:16' | System | 17 Sep 2020 14:42:51 |

US3722338

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:26:23

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| User entered '18 Sep 2020 11:59' | System | 17 Sep 2020 14:42:51 |

US3722338

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| Data entry locked. | System | 17 Sep 2020 14:42:51 |
| User entered 'Day 2' | System | 17 Sep 2020 14:42:51 |

US3722338

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:26:23

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-18T14:54:36', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'af50c491-73e5-45cd-b8d2-9c4b5df2045f' | System | 18 Sep 2020 18:55:01 |
| User entered 'Yes (Y)' | System | 18 Sep 2020 18:55:01 |

US3722338

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:26:23

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-18T14:54:44', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'af50c491-73e5-45cd-b8d2-9c4b5df2045f' | System | 18 Sep 2020 18:55:01 |
| User entered '97.3' | System | 18 Sep 2020 18:55:01 |

US3722338

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-18T14:54:50', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'af50c491-73e5-45cd-b8d2-9c4b5df2045f' | System | 18 Sep 2020 18:55:01 |
| User entered 'No (N)' | System | 18 Sep 2020 18:55:01 |

US3722338

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:26:23

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-18T14:54:55', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'af50c491-73e5-45cd-b8d2-9c4b5df2045f' | System | 18 Sep 2020 18:55:01 |
| User entered '18 Sep 2020 14:54' | System | 18 Sep 2020 18:55:01 |

US3722338

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:26:23

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| User entered '18 Sep 2020 12:00' | System | 17 Sep 2020 14:42:51 |

US3722338

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:26:23

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| User entered '19 Sep 2020 11:59' | System | 17 Sep 2020 14:42:51 |

US3722338

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| Data entry locked. | System | 17 Sep 2020 14:42:51 |
| User entered 'Day 3' | System | 17 Sep 2020 14:42:51 |

US3722338

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:26:23

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-19T12:06:54', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '6aa06610-a32b-4512-a779-c3ead7ea4e4d' | System | 19 Sep 2020 16:07:13 |
| User entered 'Yes (Y)' | System | 19 Sep 2020 16:07:13 |

US3722338

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:26:23

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-19T12:07:01', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '6aa06610-a32b-4512-a779-c3ead7ea4e4d' | System | 19 Sep 2020 16:07:13 |
| User entered '97.1' | System | 19 Sep 2020 16:07:13 |

US3722338

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-19T12:07:05', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '6aa06610-a32b-4512-a779-c3ead7ea4e4d' | System | 19 Sep 2020 16:07:13 |
| User entered 'No (N)' | System | 19 Sep 2020 16:07:13 |

US3722338

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:26:23

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-19T12:07:11', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '6aa06610-a32b-4512-a779-c3ead7ea4e4d' | System | 19 Sep 2020 16:07:13 |
| User entered '19 Sep 2020 12:07' | System | 19 Sep 2020 16:07:13 |

US3722338

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:26:23

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| User entered '19 Sep 2020 12:00' | System | 17 Sep 2020 14:42:51 |

US3722338

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:26:23

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| User entered '20 Sep 2020 11:59' | System | 17 Sep 2020 14:42:51 |

US3722338

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| Data entry locked. | System | 17 Sep 2020 14:42:51 |
| User entered 'Day 4' | System | 17 Sep 2020 14:42:51 |

US3722338

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:26:23

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-20T13:06:05', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '750f60be-b6a8-4af0-95c4-e3ee3de80f05' | System | 20 Sep 2020 17:06:24 |
| User entered 'Yes (Y)' | System | 20 Sep 2020 17:06:24 |

US3722338

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:26:23

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-20T13:06:11', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '750f60be-b6a8-4af0-95c4-e3ee3de80f05' | System | 20 Sep 2020 17:06:24 |
| User entered '97.7' | System | 20 Sep 2020 17:06:24 |

US3722338

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-20T13:06:15', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '750f60be-b6a8-4af0-95c4-e3ee3de80f05' | System | 20 Sep 2020 17:06:24 |
| User entered 'No (N)' | System | 20 Sep 2020 17:06:24 |

US3722338

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:26:23

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-20T13:06:18', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '750f60be-b6a8-4af0-95c4-e3ee3de80f05' | System | 20 Sep 2020 17:06:24 |
| User entered '20 Sep 2020 13:06' | System | 20 Sep 2020 17:06:24 |

US3722338

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:26:23

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| User entered '20 Sep 2020 12:00' | System | 17 Sep 2020 14:42:51 |

US3722338

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:26:23

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| User entered '21 Sep 2020 11:59' | System | 17 Sep 2020 14:42:51 |

US3722338

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| Data entry locked. | System | 17 Sep 2020 14:42:51 |
| User entered 'Day 5' | System | 17 Sep 2020 14:42:51 |

US3722338

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:26:23

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-21T14:52:17', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '99ed5963-db22-4e25-9b8b-b3cce3d97b6d' | System | 21 Sep 2020 18:52:35 |
| User entered 'Yes (Y)' | System | 21 Sep 2020 18:52:35 |

US3722338

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:26:23

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-21T14:52:24', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '99ed5963-db22-4e25-9b8b-b3cce3d97b6d' | System | 21 Sep 2020 18:52:35 |
| User entered '97.8' | System | 21 Sep 2020 18:52:35 |

US3722338

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-21T14:52:28', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '99ed5963-db22-4e25-9b8b-b3cce3d97b6d' | System | 21 Sep 2020 18:52:35 |
| User entered 'No (N)' | System | 21 Sep 2020 18:52:35 |

US3722338

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:26:23

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-21T14:52:31', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '99ed5963-db22-4e25-9b8b-b3cce3d97b6d' | System | 21 Sep 2020 18:52:35 |
| User entered '21 Sep 2020 14:52' | System | 21 Sep 2020 18:52:35 |

US3722338

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:26:23

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| User entered '21 Sep 2020 12:00' | System | 17 Sep 2020 14:42:51 |

US3722338

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:26:23

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| User entered '22 Sep 2020 11:59' | System | 17 Sep 2020 14:42:51 |

US3722338

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| Data entry locked. | System | 17 Sep 2020 14:42:51 |
| User entered 'Day 6' | System | 17 Sep 2020 14:42:51 |

US3722338

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:26:23

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-22T12:03:15', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '0b327c1d-0043-4381-b2a0-ccacc52cc49f' | System | 22 Sep 2020 16:04:31 |
| User entered 'Yes (Y)' | System | 22 Sep 2020 16:04:31 |

US3722338

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:26:23

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-22T12:03:20', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '0b327c1d-0043-4381-b2a0-ccacc52cc49f' | System | 22 Sep 2020 16:04:31 |
| User entered '96.0' | System | 22 Sep 2020 16:04:31 |

US3722338

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-22T12:03:23', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '0b327c1d-0043-4381-b2a0-ccacc52cc49f' | System | 22 Sep 2020 16:04:31 |
| User entered 'No (N)' | System | 22 Sep 2020 16:04:31 |

US3722338

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:26:23

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-22T12:03:27', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '0b327c1d-0043-4381-b2a0-ccacc52cc49f' | System | 22 Sep 2020 16:04:31 |
| User entered '22 Sep 2020 12:03' | System | 22 Sep 2020 16:04:31 |

US3722338

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:26:23

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| User entered '22 Sep 2020 12:00' | System | 17 Sep 2020 14:42:51 |

US3722338

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:26:23

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| User entered '23 Sep 2020 11:59' | System | 17 Sep 2020 14:42:51 |

US3722338

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| Data entry locked. | System | 17 Sep 2020 14:42:51 |
| User entered 'Day 7' | System | 17 Sep 2020 14:42:51 |

US3722338

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:26:23

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-23T12:03:24', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '849444ef-4b45-43a2-8249-32b0c18d90a5' | System | 23 Sep 2020 16:04:48 |
| User entered 'Yes (Y)' | System | 23 Sep 2020 16:04:48 |

US3722338

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:26:23

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-23T12:03:29', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '849444ef-4b45-43a2-8249-32b0c18d90a5' | System | 23 Sep 2020 16:04:48 |
| User entered '96.1' | System | 23 Sep 2020 16:04:48 |

US3722338

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-23T12:03:33', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '849444ef-4b45-43a2-8249-32b0c18d90a5' | System | 23 Sep 2020 16:04:48 |
| User entered 'No (N)' | System | 23 Sep 2020 16:04:48 |

US3722338

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:26:23

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-23T12:03:36', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '849444ef-4b45-43a2-8249-32b0c18d90a5' | System | 23 Sep 2020 16:04:48 |
| User entered '23 Sep 2020 12:03' | System | 23 Sep 2020 16:04:48 |

US3722338

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:26:23

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| User entered '23 Sep 2020 12:00' | System | 17 Sep 2020 14:42:51 |

US3722338

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:26:23

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| User entered '24 Sep 2020 11:59' | System | 17 Sep 2020 14:42:51 |

US3722338

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| Data entry locked. | System | 17 Sep 2020 14:42:51 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 17 Sep 2020 14:42:51 |

US3722338

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:26:23

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 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-17T11:02:44', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '422d4b44-6f66-450f-ae0c-47126f1e3f2f' | System | 17 Sep 2020 15:03:04 |
| User entered 'None (1)' | System | 17 Sep 2020 15:03:04 |

US3722338

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:26:23

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-17T11:02:48', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '422d4b44-6f66-450f-ae0c-47126f1e3f2f' | System | 17 Sep 2020 15:03:04 |
| User entered 'No (N)' | System | 17 Sep 2020 15:03:04 |

US3722338

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-17T11:02:51', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '422d4b44-6f66-450f-ae0c-47126f1e3f2f' | System | 17 Sep 2020 15:03:04 |
| User entered 'No (N)' | System | 17 Sep 2020 15:03:04 |

US3722338

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:26:23

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 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-17T11:02:56', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '422d4b44-6f66-450f-ae0c-47126f1e3f2f' | System | 17 Sep 2020 15:03:04 |
| User entered 'None (1)' | System | 17 Sep 2020 15:03:04 |

US3722338

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:26:23

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-17T11:03:01', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '422d4b44-6f66-450f-ae0c-47126f1e3f2f' User entered '17 Sep 2020 11:03' | System | 17 Sep 2020 15:03:04 |
| | System | 17 Sep 2020 15:03:04 |

US3722338

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:26:23

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| User entered '17 Sep 2020 10:51' | System | 17 Sep 2020 14:42:51 |

US3722338

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:26:23

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| User entered '17 Sep 2020 13:21' | System | 17 Sep 2020 14:42:51 |

US3722338

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| Data entry locked. | System | 17 Sep 2020 14:42:51 |
| User entered 'Day 1, after vaccination (at home)' | System | 17 Sep 2020 14:42:51 |

US3722338

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:26:23

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 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-17T18:14:13', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '5e32f0b8-8e97-4c17-8833-14ea163ed569' | System | 17 Sep 2020 22:14:30 |
| User entered 'None (1)' | System | 17 Sep 2020 22:14:30 |

US3722338

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:26:23

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-17T18:14:17', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '5e32f0b8-8e97-4c17-8833-14ea163ed569' | System | 17 Sep 2020 22:14:30 |
| User entered 'No (N)' | System | 17 Sep 2020 22:14:30 |

US3722338

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-17T18:14:20', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '5e32f0b8-8e97-4c17-8833-14ea163ed569' | System | 17 Sep 2020 22:14:30 |
| User entered 'No (N)' | System | 17 Sep 2020 22:14:30 |

US3722338

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:26:23

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 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-17T18:14:24', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '5e32f0b8-8e97-4c17-8833-14ea163ed569' | System | 17 Sep 2020 22:14:30 |
| User entered 'None (1)' | System | 17 Sep 2020 22:14:30 |

US3722338

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:26:23

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-17T18:14:27', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '5e32f0b8-8e97-4c17-8833-14ea163ed569' | System | 17 Sep 2020 22:14:30 |
| User entered '17 Sep 2020 18:14' | System | 17 Sep 2020 22:14:30 |

US3722338

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:26:23

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| User entered '17 Sep 2020 14:16' | System | 17 Sep 2020 14:42:51 |

US3722338

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:26:23

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| User entered '18 Sep 2020 11:59' | System | 17 Sep 2020 14:42:51 |

US3722338

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| Data entry locked. | System | 17 Sep 2020 14:42:51 |
| User entered 'Day 2' | System | 17 Sep 2020 14:42:51 |

US3722338

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:26:23

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 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-18T14:55:03', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'b72a8385-3f17-4461-83a2-922d8d1ecae4' | System | 18 Sep 2020 18:55:23 |
| User entered 'None (1)' | System | 18 Sep 2020 18:55:23 |

US3722338

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:26:23

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-18T14:55:07', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'b72a8385-3f17-4461-83a2-922d8d1ecae4' | System | 18 Sep 2020 18:55:23 |
| User entered 'No (N)' | System | 18 Sep 2020 18:55:23 |

US3722338

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-18T14:55:10', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'b72a8385-3f17-4461-83a2-922d8d1ecae4' | System | 18 Sep 2020 18:55:23 |
| User entered 'No (N)' | System | 18 Sep 2020 18:55:23 |

US3722338

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:26:23

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 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-18T14:55:14', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'b72a8385-3f17-4461-83a2-922d8d1ecae4' | System | 18 Sep 2020 18:55:23 |
| User entered 'None (1)' | System | 18 Sep 2020 18:55:23 |

US3722338

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:26:23

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-18T14:55:18', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'b72a8385-3f17-4461-83a2-922d8d1ecae4' | System | 18 Sep 2020 18:55:23 |
| User entered '18 Sep 2020 14:55' | System | 18 Sep 2020 18:55:23 |

US3722338

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:26:23

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| User entered '18 Sep 2020 12:00' | System | 17 Sep 2020 14:42:51 |

US3722338

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:26:23

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| User entered '19 Sep 2020 11:59' | System | 17 Sep 2020 14:42:51 |

US3722338

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| Data entry locked. | System | 17 Sep 2020 14:42:51 |
| User entered 'Day 3' | System | 17 Sep 2020 14:42:51 |

US3722338

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:26:23

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 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-19T12:07:18', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'eb7475a0-4f05-419b-95d4-066e0ea9b76d' | System | 19 Sep 2020 16:07:35 |
| User entered 'None (1)' | System | 19 Sep 2020 16:07:35 |

US3722338

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:26:23

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-19T12:07:21', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'eb7475a0-4f05-419b-95d4-066e0ea9b76d' | System | 19 Sep 2020 16:07:35 |
| User entered 'No (N)' | System | 19 Sep 2020 16:07:35 |

US3722338

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-19T12:07:25', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'eb7475a0-4f05-419b-95d4-066e0ea9b76d' | System | 19 Sep 2020 16:07:35 |
| User entered 'No (N)' | System | 19 Sep 2020 16:07:35 |

US3722338

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:26:23

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 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-19T12:07:28', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'eb7475a0-4f05-419b-95d4-066e0ea9b76d' | System | 19 Sep 2020 16:07:35 |
| User entered 'None (1)' | System | 19 Sep 2020 16:07:35 |

US3722338

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:26:23

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-19T12:07:32', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'eb7475a0-4f05-419b-95d4-066e0ea9b76d' | System | 19 Sep 2020 16:07:35 |
| User entered '19 Sep 2020 12:07' | System | 19 Sep 2020 16:07:35 |

US3722338

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:26:23

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| User entered '19 Sep 2020 12:00' | System | 17 Sep 2020 14:42:51 |

US3722338

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:26:23

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| User entered '20 Sep 2020 11:59' | System | 17 Sep 2020 14:42:51 |

US3722338

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| Data entry locked. | System | 17 Sep 2020 14:42:51 |
| User entered 'Day 4' | System | 17 Sep 2020 14:42:51 |

US3722338

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:26:23

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 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-20T13:06:24', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'eff13794-8b92-4350-b9f8-3db0da36f88c' | System | 20 Sep 2020 17:06:42 |
| User entered 'None (1)' | System | 20 Sep 2020 17:06:42 |

US3722338

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:26:23

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-20T13:06:28', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'eff13794-8b92-4350-b9f8-3db0da36f88c' | System | 20 Sep 2020 17:06:42 |
| User entered 'No (N)' | System | 20 Sep 2020 17:06:42 |

US3722338

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-20T13:06:31', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'eff13794-8b92-4350-b9f8-3db0da36f88c' | System | 20 Sep 2020 17:06:42 |
| User entered 'No (N)' | System | 20 Sep 2020 17:06:42 |

US3722338

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:26:23

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 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-20T13:06:34', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'eff13794-8b92-4350-b9f8-3db0da36f88c' | System | 20 Sep 2020 17:06:42 |
| User entered 'None (1)' | System | 20 Sep 2020 17:06:42 |

US3722338

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:26:23

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-20T13:06:37', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'eff13794-8b92-4350-b9f8-3db0da36f88c' | System | 20 Sep 2020 17:06:42 |
| User entered '20 Sep 2020 13:06' | System | 20 Sep 2020 17:06:42 |

US3722338

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:26:23

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| User entered '20 Sep 2020 12:00' | System | 17 Sep 2020 14:42:51 |

US3722338

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:26:23

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| User entered '21 Sep 2020 11:59' | System | 17 Sep 2020 14:42:51 |

US3722338

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| Data entry locked. | System | 17 Sep 2020 14:42:51 |
| User entered 'Day 5' | System | 17 Sep 2020 14:42:51 |

US3722338

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:26:23

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 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-21T14:52:37', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '5cb0928c-2382-4058-92e1-3eea6b9adc86' | System | 21 Sep 2020 18:52:54 |
| User entered 'None (1)' | System | 21 Sep 2020 18:52:54 |

US3722338

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:26:23

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-21T14:52:40', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '5cb0928c-2382-4058-92e1-3eea6b9adc86' | System | 21 Sep 2020 18:52:54 |
| User entered 'No (N)' | System | 21 Sep 2020 18:52:54 |

US3722338

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-21T14:52:43', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '5cb0928c-2382-4058-92e1-3eea6b9adc86' | System | 21 Sep 2020 18:52:54 |
| User entered 'No (N)' | System | 21 Sep 2020 18:52:54 |

US3722338

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:26:23

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 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-21T14:52:47', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '5cb0928c-2382-4058-92e1-3eea6b9adc86' | System | 21 Sep 2020 18:52:54 |
| User entered 'None (1)' | System | 21 Sep 2020 18:52:54 |

US3722338

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:26:23

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-21T14:52:50', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '5cb0928c-2382-4058-92e1-3eea6b9adc86' | System | 21 Sep 2020 18:52:54 |
| User entered '21 Sep 2020 14:52' | System | 21 Sep 2020 18:52:54 |

US3722338

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:26:23

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| User entered '21 Sep 2020 12:00' | System | 17 Sep 2020 14:42:51 |

US3722338

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:26:23

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| User entered '22 Sep 2020 11:59' | System | 17 Sep 2020 14:42:51 |

US3722338

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| Data entry locked. | System | 17 Sep 2020 14:42:51 |
| User entered 'Day 6' | System | 17 Sep 2020 14:42:51 |

US3722338

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:26:23

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 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-22T12:03:33', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'f145331f-e7ef-4b3e-a7af-1fd4d3077c0f' | System | 22 Sep 2020 16:04:47 |
| User entered 'None (1)' | System | 22 Sep 2020 16:04:47 |

US3722338

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:26:23

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-22T12:03:36', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'f145331f-e7ef-4b3e-a7af-1fd4d3077c0f' | System | 22 Sep 2020 16:04:47 |
| User entered 'No (N)' | System | 22 Sep 2020 16:04:47 |

US3722338

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-22T12:03:39', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'f145331f-e7ef-4b3e-a7af-1fd4d3077c0f' | System | 22 Sep 2020 16:04:47 |
| User entered 'No (N)' | System | 22 Sep 2020 16:04:47 |

US3722338

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:26:23

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 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-22T12:03:43', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'f145331f-e7ef-4b3e-a7af-1fd4d3077c0f' | System | 22 Sep 2020 16:04:47 |
| User entered 'None (1)' | System | 22 Sep 2020 16:04:47 |

US3722338

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:26:23

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-22T12:03:46', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'f145331f-e7ef-4b3e-a7af-1fd4d3077c0f' User entered '22 Sep 2020 12:03' | System | 22 Sep 2020 16:04:47 |
| | System | 22 Sep 2020 16:04:47 |

US3722338

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:26:23

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| User entered '22 Sep 2020 12:00' | System | 17 Sep 2020 14:42:51 |

US3722338

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:26:23

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| User entered '23 Sep 2020 11:59' | System | 17 Sep 2020 14:42:51 |

US3722338

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| Data entry locked. | System | 17 Sep 2020 14:42:51 |
| User entered 'Day 7' | System | 17 Sep 2020 14:42:51 |

US3722338

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:26:23

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 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-23T12:03:42', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'c31b02be-533d-4a3c-afa6-e4a99cb80ed9' | System | 23 Sep 2020 16:05:01 |
| User entered 'None (1)' | System | 23 Sep 2020 16:05:01 |

US3722338

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:26:23

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-23T12:03:45', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'c31b02be-533d-4a3c-afa6-e4a99cb80ed9' | System | 23 Sep 2020 16:05:01 |
| User entered 'No (N)' | System | 23 Sep 2020 16:05:01 |

US3722338

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-23T12:03:48', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'c31b02be-533d-4a3c-afa6-e4a99cb80ed9' | System | 23 Sep 2020 16:05:01 |
| User entered 'No (N)' | System | 23 Sep 2020 16:05:01 |

US3722338

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:26:23

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 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-23T12:03:52', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'c31b02be-533d-4a3c-afa6-e4a99cb80ed9' | System | 23 Sep 2020 16:05:01 |
| User entered 'None (1)' | System | 23 Sep 2020 16:05:01 |

US3722338

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:26:23

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-23T12:03:56', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'c31b02be-533d-4a3c-afa6-e4a99cb80ed9' | System | 23 Sep 2020 16:05:01 |
| User entered '23 Sep 2020 12:03' | System | 23 Sep 2020 16:05:01 |

US3722338

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:26:23

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| User entered '23 Sep 2020 12:00' | System | 17 Sep 2020 14:42:51 |

US3722338

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:26:23

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| User entered '24 Sep 2020 11:59' | System | 17 Sep 2020 14:42:51 |

US3722338

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| Data entry locked. | System | 17 Sep 2020 14:42:51 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 17 Sep 2020 14:42:51 |

US3722338

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:26:23

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-17T11:03:07', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '86b0287e-e745-42ea-8d37-4aec58e88113' | System | 17 Sep 2020 15:03:34 |
| User entered 'None (0)' | System | 17 Sep 2020 15:03:34 |

US3722338

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:26:23

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-17T11:03:10', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '86b0287e-e745-42ea-8d37-4aec58e88113' | System | 17 Sep 2020 15:03:34 |
| User entered 'None (0)' | System | 17 Sep 2020 15:03:34 |

US3722338

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:26:23

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-17T11:03:13', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '86b0287e-e745-42ea-8d37-4aec58e88113' | System | 17 Sep 2020 15:03:34 |
| User entered 'None (0)' | System | 17 Sep 2020 15:03:34 |

US3722338

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:26:23

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-17T11:03:16', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '86b0287e-e745-42ea-8d37-4aec58e88113' | System | 17 Sep 2020 15:03:34 |
| User entered 'None (0)' | System | 17 Sep 2020 15:03:34 |

US3722338

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:26:23

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-17T11:03:19', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '86b0287e-e745-42ea-8d37-4aec58e88113' | System | 17 Sep 2020 15:03:34 |
| User entered 'None (0)' | System | 17 Sep 2020 15:03:34 |

US3722338

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:26:23

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-17T11:03:22', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '86b0287e-e745-42ea-8d37-4aec58e88113' | System | 17 Sep 2020 15:03:34 |
| User entered 'None (0)' | System | 17 Sep 2020 15:03:34 |

US3722338

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:26:23

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 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-17T11:03:26', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '86b0287e-e745-42ea-8d37-4aec58e88113' | System | 17 Sep 2020 15:03:34 |
| User entered 'No (N)' | System | 17 Sep 2020 15:03:34 |

US3722338

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:26:23

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-17T11:03:31', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '86b0287e-e745-42ea-8d37-4aec58e88113' | System | 17 Sep 2020 15:03:34 |
| User entered '17 Sep 2020 11:03' | System | 17 Sep 2020 15:03:34 |

US3722338

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:26:23

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| User entered '17 Sep 2020 10:51' | System | 17 Sep 2020 14:42:51 |

US3722338

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:26:23

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| User entered '17 Sep 2020 13:21' | System | 17 Sep 2020 14:42:51 |

US3722338

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| Data entry locked. | System | 17 Sep 2020 14:42:51 |
| User entered 'Day 1, after vaccination (at home)' | System | 17 Sep 2020 14:42:51 |

US3722338

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:26:23

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-17T18:14:34', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '1957cbb2-a85f-4343-8f1f-d7b42b312080' | System | 17 Sep 2020 22:15:02 |
| User entered 'None (0)' | System | 17 Sep 2020 22:15:02 |

US3722338

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:26:23

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-17T18:14:36', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '1957cbb2-a85f-4343-8f1f-d7b42b312080' | System | 17 Sep 2020 22:15:02 |
| User entered 'None (0)' | System | 17 Sep 2020 22:15:02 |

US3722338

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:26:23

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-17T18:14:39', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '1957cbb2-a85f-4343-8f1f-d7b42b312080' | System | 17 Sep 2020 22:15:02 |
| User entered 'None (0)' | System | 17 Sep 2020 22:15:02 |

US3722338

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:26:23

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-17T18:14:42', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '1957cbb2-a85f-4343-8f1f-d7b42b312080' | System | 17 Sep 2020 22:15:02 |
| User entered 'None (0)' | System | 17 Sep 2020 22:15:02 |

US3722338

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:26:23

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-17T18:14:45', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '1957cbb2-a85f-4343-8f1f-d7b42b312080' | System | 17 Sep 2020 22:15:02 |
| User entered 'None (0)' | System | 17 Sep 2020 22:15:02 |

US3722338

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:26:23

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-17T18:14:48', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '1957cbb2-a85f-4343-8f1f-d7b42b312080' | System | 17 Sep 2020 22:15:02 |
| User entered 'None (0)' | System | 17 Sep 2020 22:15:02 |

US3722338

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:26:23

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 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-17T18:14:52', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '1957cbb2-a85f-4343-8f1f-d7b42b312080' | System | 17 Sep 2020 22:15:02 |
| User entered 'No (N)' | System | 17 Sep 2020 22:15:02 |

US3722338

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:26:23

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-17T18:14:56', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '1957cbb2-a85f-4343-8f1f-d7b42b312080' | System | 17 Sep 2020 22:15:02 |
| User entered '17 Sep 2020 18:14' | System | 17 Sep 2020 22:15:02 |

US3722338

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:26:23

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| User entered '17 Sep 2020 14:16' | System | 17 Sep 2020 14:42:51 |

US3722338

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:26:23

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| User entered '18 Sep 2020 11:59' | System | 17 Sep 2020 14:42:51 |

US3722338

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| Data entry locked. | System | 17 Sep 2020 14:42:51 |
| User entered 'Day 2' | System | 17 Sep 2020 14:42:51 |

US3722338

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:26:23

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-18T14:55:26', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'e539ef00-0c08-4edc-a149-a3d8e8c31348' | System | 18 Sep 2020 18:56:01 |
| User entered 'No interference with activity (1)' | System | 18 Sep 2020 18:56:01 |

US3722338

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:26:23

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-18T14:55:31', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'e539ef00-0c08-4edc-a149-a3d8e8c31348' | System | 18 Sep 2020 18:56:01 |
| User entered 'Some interference with activity (2)' | System | 18 Sep 2020 18:56:01 |

US3722338

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:26:23

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-18T14:55:37', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'e539ef00-0c08-4edc-a149-a3d8e8c31348' | System | 18 Sep 2020 18:56:01 |
| User entered 'None (0)' | System | 18 Sep 2020 18:56:01 |

US3722338

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:26:23

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-18T14:55:43', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'e539ef00-0c08-4edc-a149-a3d8e8c31348' | System | 18 Sep 2020 18:56:01 |
| User entered 'No interference with activity (1)' | System | 18 Sep 2020 18:56:01 |

US3722338

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:26:23

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-18T14:55:45', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'e539ef00-0c08-4edc-a149-a3d8e8c31348' | System | 18 Sep 2020 18:56:01 |
| User entered 'None (0)' | System | 18 Sep 2020 18:56:01 |

US3722338

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:26:23

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-18T14:55:48', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'e539ef00-0c08-4edc-a149-a3d8e8c31348' | System | 18 Sep 2020 18:56:01 |
| User entered 'None (0)' | System | 18 Sep 2020 18:56:01 |

US3722338

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:26:23

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 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-18T14:55:54', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'e539ef00-0c08-4edc-a149-a3d8e8c31348' | System | 18 Sep 2020 18:56:01 |
| User entered 'No (N)' | System | 18 Sep 2020 18:56:01 |

US3722338

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:26:23

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-18T14:55:58', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'e539ef00-0c08-4edc-a149-a3d8e8c31348' | System | 18 Sep 2020 18:56:01 |
| User entered '18 Sep 2020 14:55' | System | 18 Sep 2020 18:56:01 |

US3722338

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:26:23

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| User entered '18 Sep 2020 12:00' | System | 17 Sep 2020 14:42:51 |

US3722338

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:26:23

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| User entered '19 Sep 2020 11:59' | System | 17 Sep 2020 14:42:51 |

US3722338

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| Data entry locked. | System | 17 Sep 2020 14:42:51 |
| User entered 'Day 3' | System | 17 Sep 2020 14:42:51 |

US3722338

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:26:23

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-19T12:07:38', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '9339dfa8-57af-4f94-99c5-2bfc78775795' | System | 19 Sep 2020 16:08:01 |
| User entered 'None (0)' | System | 19 Sep 2020 16:08:01 |

US3722338

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:26:23

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-19T12:07:41', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '9339dfa8-57af-4f94-99c5-2bfc78775795' | System | 19 Sep 2020 16:08:01 |
| User entered 'None (0)' | System | 19 Sep 2020 16:08:01 |

US3722338

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:26:23

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-19T12:07:43', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '9339dfa8-57af-4f94-99c5-2bfc78775795' | System | 19 Sep 2020 16:08:01 |
| User entered 'None (0)' | System | 19 Sep 2020 16:08:01 |

US3722338

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:26:23

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-19T12:07:46', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '9339dfa8-57af-4f94-99c5-2bfc78775795' | System | 19 Sep 2020 16:08:01 |
| User entered 'None (0)' | System | 19 Sep 2020 16:08:01 |

US3722338

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:26:23

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-19T12:07:49', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '9339dfa8-57af-4f94-99c5-2bfc78775795' | System | 19 Sep 2020 16:08:01 |
| User entered 'None (0)' | System | 19 Sep 2020 16:08:01 |

US3722338

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:26:23

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-19T12:07:52', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '9339dfa8-57af-4f94-99c5-2bfc78775795' | System | 19 Sep 2020 16:08:01 |
| User entered 'None (0)' | System | 19 Sep 2020 16:08:01 |

US3722338

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:26:23

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 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-19T12:07:56', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '9339dfa8-57af-4f94-99c5-2bfc78775795' | System | 19 Sep 2020 16:08:01 |
| User entered 'No (N)' | System | 19 Sep 2020 16:08:01 |

US3722338

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:26:23

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-19T12:07:59', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '9339dfa8-57af-4f94-99c5-2bfc78775795' | System | 19 Sep 2020 16:08:01 |
| User entered '19 Sep 2020 12:07' | System | 19 Sep 2020 16:08:01 |

US3722338

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:26:23

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| User entered '19 Sep 2020 12:00' | System | 17 Sep 2020 14:42:51 |

US3722338

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:26:23

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| User entered '20 Sep 2020 11:59' | System | 17 Sep 2020 14:42:51 |

US3722338

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| Data entry locked. | System | 17 Sep 2020 14:42:51 |
| User entered 'Day 4' | System | 17 Sep 2020 14:42:51 |

US3722338

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:26:23

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-20T13:06:43', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'a188ad5a-7ae3-4770-8b0f-ca516bac3404' | System | 20 Sep 2020 17:07:18 |
| User entered 'None (0)' | System | 20 Sep 2020 17:07:18 |

US3722338

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:26:23

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-20T13:06:46', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'a188ad5a-7ae3-4770-8b0f-ca516bac3404' | System | 20 Sep 2020 17:07:18 |
| User entered 'None (0)' | System | 20 Sep 2020 17:07:18 |

US3722338

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:26:23

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-20T13:06:49', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'a188ad5a-7ae3-4770-8b0f-ca516bac3404' | System | 20 Sep 2020 17:07:18 |
| User entered 'None (0)' | System | 20 Sep 2020 17:07:18 |

US3722338

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:26:23

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-20T13:06:52', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'a188ad5a-7ae3-4770-8b0f-ca516bac3404' | System | 20 Sep 2020 17:07:18 |
| User entered 'None (0)' | System | 20 Sep 2020 17:07:18 |

US3722338

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:26:23

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-20T13:06:55', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'a188ad5a-7ae3-4770-8b0f-ca516bac3404' | System | 20 Sep 2020 17:07:18 |
| User entered 'None (0)' | System | 20 Sep 2020 17:07:18 |

US3722338

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:26:23

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-20T13:06:57', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'a188ad5a-7ae3-4770-8b0f-ca516bac3404' | System | 20 Sep 2020 17:07:18 |
| User entered 'None (0)' | System | 20 Sep 2020 17:07:18 |

US3722338

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:26:23

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 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-20T13:07:03', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'a188ad5a-7ae3-4770-8b0f-ca516bac3404' | System | 20 Sep 2020 17:07:18 |
| User entered 'No (N)' | System | 20 Sep 2020 17:07:18 |

US3722338

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:26:23

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-20T13:07:13', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'a188ad5a-7ae3-4770-8b0f-ca516bac3404' | System | 20 Sep 2020 17:07:18 |
| User entered '20 Sep 2020 13:07' | System | 20 Sep 2020 17:07:18 |

US3722338

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:26:23

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| User entered '20 Sep 2020 12:00' | System | 17 Sep 2020 14:42:51 |

US3722338

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:26:23

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| User entered '21 Sep 2020 11:59' | System | 17 Sep 2020 14:42:51 |

US3722338

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| Data entry locked. | System | 17 Sep 2020 14:42:51 |
| User entered 'Day 5' | System | 17 Sep 2020 14:42:51 |

US3722338

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:26:23

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-21T14:52:56', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '1bb70508-0f76-4e80-ab5f-9ee8e17cf09a' | System | 21 Sep 2020 18:53:21 |
| User entered 'None (0)' | System | 21 Sep 2020 18:53:21 |

US3722338

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:26:23

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-21T14:52:59', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '1bb70508-0f76-4e80-ab5f-9ee8e17cf09a' | System | 21 Sep 2020 18:53:21 |
| User entered 'None (0)' | System | 21 Sep 2020 18:53:21 |

US3722338

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:26:23

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-21T14:53:02', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '1bb70508-0f76-4e80-ab5f-9ee8e17cf09a' | System | 21 Sep 2020 18:53:21 |
| User entered 'None (0)' | System | 21 Sep 2020 18:53:21 |

US3722338

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:26:23

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-21T14:53:04', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '1bb70508-0f76-4e80-ab5f-9ee8e17cf09a' | System | 21 Sep 2020 18:53:21 |
| User entered 'None (0)' | System | 21 Sep 2020 18:53:21 |

US3722338

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:26:23

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-21T14:53:07', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '1bb70508-0f76-4e80-ab5f-9ee8e17cf09a' | System | 21 Sep 2020 18:53:21 |
| User entered 'None (0)' | System | 21 Sep 2020 18:53:21 |

US3722338

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:26:23

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-21T14:53:10', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '1bb70508-0f76-4e80-ab5f-9ee8e17cf09a' | System | 21 Sep 2020 18:53:21 |
| User entered 'None (0)' | System | 21 Sep 2020 18:53:21 |

US3722338

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:26:23

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 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-21T14:53:13', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '1bb70508-0f76-4e80-ab5f-9ee8e17cf09a' | System | 21 Sep 2020 18:53:21 |
| User entered 'No (N)' | System | 21 Sep 2020 18:53:21 |

US3722338

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:26:23

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-21T14:53:16', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '1bb70508-0f76-4e80-ab5f-9ee8e17cf09a' | System | 21 Sep 2020 18:53:21 |
| User entered '21 Sep 2020 14:53' | System | 21 Sep 2020 18:53:21 |

US3722338

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:26:23

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| User entered '21 Sep 2020 12:00' | System | 17 Sep 2020 14:42:51 |

US3722338

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:26:23

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| User entered '22 Sep 2020 11:59' | System | 17 Sep 2020 14:42:51 |

US3722338

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| Data entry locked. | System | 17 Sep 2020 14:42:51 |
| User entered 'Day 6' | System | 17 Sep 2020 14:42:51 |

US3722338

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:26:23

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-22T12:03:51', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '5a556d2f-dfc5-4434-a895-86138fc63961' | System | 22 Sep 2020 16:05:00 |
| User entered 'None (0)' | System | 22 Sep 2020 16:05:00 |

US3722338

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:26:23

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-22T12:03:54', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '5a556d2f-dfc5-4434-a895-86138fc63961' | System | 22 Sep 2020 16:05:00 |
| User entered 'None (0)' | System | 22 Sep 2020 16:05:00 |

US3722338

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:26:23

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-22T12:03:58', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '5a556d2f-dfc5-4434-a895-86138fc63961' | System | 22 Sep 2020 16:05:00 |
| User entered 'None (0)' | System | 22 Sep 2020 16:05:00 |

US3722338

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:26:23

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-22T12:04:01', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '5a556d2f-dfc5-4434-a895-86138fc63961' | System | 22 Sep 2020 16:05:00 |
| User entered 'None (0)' | System | 22 Sep 2020 16:05:00 |

US3722338

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:26:23

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-22T12:04:04', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '5a556d2f-dfc5-4434-a895-86138fc63961' | System | 22 Sep 2020 16:05:00 |
| User entered 'None (0)' | System | 22 Sep 2020 16:05:00 |

US3722338

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:26:23

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-22T12:04:07', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '5a556d2f-dfc5-4434-a895-86138fc63961' | System | 22 Sep 2020 16:05:00 |
| User entered 'None (0)' | System | 22 Sep 2020 16:05:00 |

US3722338

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:26:23

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 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-22T12:04:11', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '5a556d2f-dfc5-4434-a895-86138fc63961' | System | 22 Sep 2020 16:05:00 |
| User entered 'No (N)' | System | 22 Sep 2020 16:05:00 |

US3722338

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:26:23

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-22T12:04:14', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '5a556d2f-dfc5-4434-a895-86138fc63961' | System | 22 Sep 2020 16:05:00 |
| User entered '22 Sep 2020 12:04' | System | 22 Sep 2020 16:05:00 |

US3722338

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:26:23

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| User entered '22 Sep 2020 12:00' | System | 17 Sep 2020 14:42:51 |

US3722338

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:26:23

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| User entered '23 Sep 2020 11:59' | System | 17 Sep 2020 14:42:51 |

US3722338

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| Data entry locked. | System | 17 Sep 2020 14:42:51 |
| User entered 'Day 7' | System | 17 Sep 2020 14:42:51 |

US3722338

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:26:23

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-23T12:04:02', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '0b25c741-7cef-4124-9117-cc216eb815a1' | System | 23 Sep 2020 16:05:24 |
| User entered 'None (0)' | System | 23 Sep 2020 16:05:24 |

US3722338

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:26:23

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-23T12:04:04', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '0b25c741-7cef-4124-9117-cc216eb815a1' | System | 23 Sep 2020 16:05:24 |
| User entered 'None (0)' | System | 23 Sep 2020 16:05:24 |

US3722338

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:26:23

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-23T12:04:07', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '0b25c741-7cef-4124-9117-cc216eb815a1' | System | 23 Sep 2020 16:05:24 |
| User entered 'None (0)' | System | 23 Sep 2020 16:05:24 |

US3722338

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:26:23

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-23T12:04:10', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '0b25c741-7cef-4124-9117-cc216eb815a1' | System | 23 Sep 2020 16:05:24 |
| User entered 'None (0)' | System | 23 Sep 2020 16:05:24 |

US3722338

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:26:23

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-23T12:04:12', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '0b25c741-7cef-4124-9117-cc216eb815a1' | System | 23 Sep 2020 16:05:24 |
| User entered 'None (0)' | System | 23 Sep 2020 16:05:24 |

US3722338

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:26:23

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-23T12:04:15', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '0b25c741-7cef-4124-9117-cc216eb815a1' | System | 23 Sep 2020 16:05:24 |
| User entered 'None (0)' | System | 23 Sep 2020 16:05:24 |

US3722338

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:26:23

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 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-23T12:04:19', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '0b25c741-7cef-4124-9117-cc216eb815a1' | System | 23 Sep 2020 16:05:24 |
| User entered 'No (N)' | System | 23 Sep 2020 16:05:24 |

US3722338

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:26:23

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-09-23T12:04:21', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '0b25c741-7cef-4124-9117-cc216eb815a1' | System | 23 Sep 2020 16:05:24 |
| User entered '23 Sep 2020 12:04' | System | 23 Sep 2020 16:05:24 |

US3722338

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:26:23

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| User entered '23 Sep 2020 12:00' | System | 17 Sep 2020 14:42:51 |

US3722338

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:26:23

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:35:10 |
| User entered '24 Sep 2020 11:59' | System | 17 Sep 2020 14:42:51 |

US3722338

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:26:23

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered 'Yes (Y)' | Amy Ford (b) (4) | 25 Sep 2020 16:00:25 |

US3722338

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:26:23

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered '24 Sep 2020' | Amy Ford (b) (4) | 25 Sep 2020 16:00:25 |

US3722338

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:26:23

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered 'Contact Made (CONTACT MADE)' | Amy Ford (b) (4) | 25 Sep 2020 16:00:25 |

US3722338

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:26:23

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered empty. | Amy Ford (b) (4) | 25 Sep 2020 16:00:25 |

US3722338

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:26:23

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered 'Yes (Y)' | Amy Ford (b) (4) | 25 Sep 2020 16:00:31 |

US3722338

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:26:23

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User entered 'I' | System | 25 Sep 2020 16:00:31 |

US3722338

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:26:23

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered 'Yes (Y)' | Kayla Peay (b) (4) | 16 Oct 2020 14:34:24 |

US3722338

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:26:23

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User closed query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System). | (b) (4) (b) (4), (b) (6) | 26 Oct 2020 08:59:39 |
| Query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Per source, date is correct. ' (Site from System). | Kayla Peay (b) (4) (b) (4) | 16 Oct 2020 14:34:35 |
| User opened query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System). | System | 16 Oct 2020 14:34:24 |
| User entered '8 Oct 2020' | Kayla Peay (b) (4) (b) (4) | 16 Oct 2020 14:34:24 |

US3722338

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:26:23

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered 'Contact Not Made (CONTACT NOT MADE)' | Kayla Peay (b) (4) | 16 Oct 2020 14:34:24 |

US3722338

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:26:23

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered 'Multiple attempts made; but ultimately unsuccessful.' | Kayla Peay (b) (4) | 16 Oct 2020 14:34:24 |

US3722338

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:26:23

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered 'Yes (Y)' | Kayla Peay (b) (4) | 16 Oct 2020 14:34:41 |

US3722338

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:26:23

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User entered 'I' | System | 16 Oct 2020 14:34:41 |

US3722338

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:26:23

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered 'Yes (Y)' | Kayla Peay (b) (4) | 21 Oct 2020 14:01:57 |

US3722338

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:26:23

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered '08 Oct 2020' | Kayla Peay (b) (4) | 21 Oct 2020 14:01:57 |

US3722338

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:26:23

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered 'Contact Made (CONTACT MADE)' | Kayla Peay (b) (4) | 21 Oct 2020 14:01:57 |

US3722338

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:26:23

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered empty. | Kayla Peay (b) (4) | 21 Oct 2020 14:01:57 |

US3722338

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:26:23

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered 'Yes (Y)' | Marlee Smith (b) (4) | 21 Oct 2020 17:50:56 |

US3722338

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:26:23

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User entered 'I' | System | 21 Oct 2020 17:50:56 |

US3722338

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:26:23

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered 'No (N)' | Marlee Smith (b) (4) | 23 Nov 2020 20:33:26 |

US3722338

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered empty. | Marlee Smith (b) (4) | 23 Nov 2020 20:33:26 |

US3722338

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered empty. | Marlee Smith (b) (4) | 23 Nov 2020 20:33:26 |

US3722338

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:26:23

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User entered 'VISIT3' | System | 23 Nov 2020 20:33:26 |

US3722338

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:26:23

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered 'No (N)' | Marlee Smith (b) (4) | 23 Nov 2020 20:33:31 |

US3722338

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:26:23

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered empty. | Marlee Smith (b) (4) | 23 Nov 2020 20:33:31 |

US3722338

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered empty. | Marlee Smith (b) (4) | 23 Nov 2020 20:33:31 |

US3722338

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User entered empty. | System | 23 Nov 2020 20:33:31 |

US3722338

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:26:23

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered empty. | Marlee Smith (b) (4) | 23 Nov 2020 20:33:31 |

US3722338

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:26:23

[Route of measurement](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered empty. | Marlee Smith (b) (4) | 23 Nov 2020 20:33:31 |

US3722338

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:26:23

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered empty. | Marlee Smith (b) (4) | 23 Nov 2020 20:33:31 |

US3722338

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:26:23

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered empty. | Marlee Smith (b) (4) | 23 Nov 2020 20:33:31 |

US3722338

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:26:23

[Pulse units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User entered empty. | System | 23 Nov 2020 20:33:31 |

US3722338

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered empty. | Marlee Smith (b) (4) | 23 Nov 2020 20:33:31 |

US3722338

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:26:23

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User entered empty. | System | 23 Nov 2020 20:33:31 |

US3722338

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:26:23

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered empty. | Marlee Smith (b) (4) | 23 Nov 2020 20:33:31 |

US3722338

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:26:23

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User entered empty. | System | 23 Nov 2020 20:33:31 |

US3722338

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:26:23

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered empty. | Marlee Smith (b) (4) | 23 Nov 2020 20:33:31 |

US3722338

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:26:23

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User entered empty. | System | 23 Nov 2020 20:33:31 |

US3722338

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:26:23

[Height \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| | | |

US3722338

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:26:23

Weight (derived)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |

US3722338

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:26:23

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered 'No (N)' | Marlee Smith (b) (4) | 23 Nov 2020 20:33:37 |

US3722338

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:26:23

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered empty. | Marlee Smith (b) (4) | 23 Nov 2020 20:33:37 |

US3722338

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:26:23

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered 'No (N)' | Marlee Smith (b) (4) | 23 Nov 2020 20:33:39 |

US3722338

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:26:23

Collection date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered empty. | Marlee Smith (b) (4) | 23 Nov 2020 20:33:39 |

US3722338

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:26:23

Collection time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered empty. | Marlee Smith (b) (4) | 23 Nov 2020 20:33:39 |

US3722338

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:26:23

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User entered empty. | System | 23 Nov 2020 20:33:39 |

US3722338

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:26:23

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Marlee Smith (b) (4) | 11 Feb 2021 18:41:13 |
| User entered 'No (N)' | Marlee Smith (b) (4) | 23 Nov 2020 20:33:42 |

US3722338

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:26:23

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User entered '1' | System | 11 Feb 2021 18:41:13 |
| User entered empty. | System | 23 Nov 2020 20:33:42 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |
| Data entry locked. | System | 20 Aug 2020 17:36:06 |
| User entered 'Day 64' | System | 20 Aug 2020 17:36:06 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

Fever (Temperature \geq 100.4°F/38°C)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Chills](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Cough](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Shortness of breath](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Difficulty breathing](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Fatigue](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Muscle aches](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Body aches](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Headache](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[New loss of taste](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[New loss of smell](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Sore throat](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Congestion](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Runny nose](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Nausea](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Vomiting](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Diarrhea](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |
| Data entry locked. | System | 20 Aug 2020 17:36:06 |
| User entered '20 Oct 2020 00:01' | System | 20 Aug 2020 17:36:06 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |
| Data entry locked. | System | 20 Aug 2020 17:36:06 |
| User entered '24 Oct 2020 23:59' | System | 20 Aug 2020 17:36:06 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |
| Data entry locked. | System | 20 Aug 2020 17:36:06 |
| User entered 'Day 71' | System | 20 Aug 2020 17:36:06 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

Fever (Temperature \geq 100.4°F/38°C)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Chills](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Cough](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Shortness of breath](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Difficulty breathing](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Fatigue](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Muscle aches](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Body aches](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Headache](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[New loss of taste](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[New loss of smell](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Sore throat](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Congestion](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Runny nose](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Nausea](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Vomiting](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Diarrhea](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |
| Data entry locked. | System | 20 Aug 2020 17:36:06 |
| User entered '27 Oct 2020 00:01' | System | 20 Aug 2020 17:36:06 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |
| Data entry locked. | System | 20 Aug 2020 17:36:06 |
| User entered '31 Oct 2020 23:59' | System | 20 Aug 2020 17:36:06 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |
| Data entry locked. | System | 20 Aug 2020 17:36:06 |
| User entered 'Day 78' | System | 20 Aug 2020 17:36:06 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

Fever (Temperature \geq 100.4°F/38°C)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Chills](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Cough](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Shortness of breath](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Difficulty breathing](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Fatigue](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Muscle aches](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Body aches](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Headache](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[New loss of taste](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[New loss of smell](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Sore throat](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Congestion](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Runny nose](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Nausea](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Vomiting](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Diarrhea](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |
| Data entry locked. | System | 20 Aug 2020 17:36:06 |
| User entered '03 Nov 2020 00:01' | System | 20 Aug 2020 17:36:06 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |
| Data entry locked. | System | 20 Aug 2020 17:36:06 |
| User entered '07 Nov 2020 23:59' | System | 20 Aug 2020 17:36:06 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |
| Data entry locked. | System | 20 Aug 2020 17:36:06 |
| User entered 'Day 92' | System | 20 Aug 2020 17:36:06 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

Fever (Temperature \geq 100.4°F/38°C)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Chills](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Cough](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Shortness of breath](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Difficulty breathing](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Fatigue](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Muscle aches](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Body aches](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Headache](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[New loss of taste](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[New loss of smell](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Sore throat](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Congestion](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Runny nose](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Nausea](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Vomiting](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Diarrhea](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |
| Data entry locked. | System | 20 Aug 2020 17:36:06 |
| User entered '17 Nov 2020 00:01' | System | 20 Aug 2020 17:36:06 |

US3722338

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:49:23 |
| Data entry locked. | System | 20 Aug 2020 17:36:06 |
| User entered '21 Nov 2020 23:59' | System | 20 Aug 2020 17:36:06 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered 'Day 96' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '21 Nov 2020 00:01' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '25 Nov 2020 23:59' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered 'Day 103' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '28 Nov 2020 00:01' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '02 Dec 2020 23:59' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered 'Day 110' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '05 Dec 2020 00:01' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '09 Dec 2020 23:59' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered 'Day 117' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '12 Dec 2020 00:01' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '16 Dec 2020 23:59' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered 'Day 124' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[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 (0e2f00a6ea3c005e)', Time: '2020-12-23T08:35:11', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '03e20f11-2239-4301-b9d8-c9847ddd95a0' | System | 23 Dec 2020 13:36:04 |
| User entered 'Yes (Y)' | System | 23 Dec 2020 13:36:04 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

Have you been exposed to someone with 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 (0e2f00a6ea3c005e)', Time: '2020-12-23T08:35:16', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '03e20f11-2239-4301-b9d8-c9847ddd95a0' | System | 23 Dec 2020 13:36:04 |
| User entered 'No (N)' | System | 23 Dec 2020 13:36:04 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-12-23T08:35:22', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '03e20f11-2239-4301-b9d8-c9847ddd95a0' | System | 23 Dec 2020 13:36:04 |
| User entered 'No (N)' | System | 23 Dec 2020 13:36:04 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-12-23T08:35:30', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '03e20f11-2239-4301-b9d8-c9847ddd95a0' | System | 23 Dec 2020 13:36:04 |
| User entered 'Yes (Y)' | System | 23 Dec 2020 13:36:04 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-12-23T08:35:39', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '03e20f11-2239-4301-b9d8-c9847ddd95a0' | System | 23 Dec 2020 13:36:04 |
| User entered 'I confirm I have read this message and will call the study clinic immediately (9)' | System | 23 Dec 2020 13:36:04 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-12-23T08:35:50', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '03e20f11-2239-4301-b9d8-c9847ddd95a0' | System | 23 Dec 2020 13:36:04 |
| User entered '23 Dec 2020 08:35:50' | System | 23 Dec 2020 13:36:04 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '19 Dec 2020 00:01' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '23 Dec 2020 23:59' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered 'Day 131' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[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 (0e2f00a6ea3c005e)', Time: '2020-12-26T02:04:39', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '30af1843-600d-49ea-9594-52451ccf59d1' | System | 26 Dec 2020 07:04:53 |
| User entered 'No (N)' | System | 26 Dec 2020 07:04:53 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

Have you been exposed to someone with 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 (0e2f00a6ea3c005e)', Time: '2020-12-26T02:04:43', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '30af1843-600d-49ea-9594-52451ccf59d1' | System | 26 Dec 2020 07:04:53 |
| User entered 'No (N)' | System | 26 Dec 2020 07:04:53 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2020-12-26T02:04:50', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '30af1843-600d-49ea-9594-52451ccf59d1' | System | 26 Dec 2020 07:04:53 |
| User entered '26 Dec 2020 02:04:50' | System | 26 Dec 2020 07:04:53 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '26 Dec 2020 00:01' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '30 Dec 2020 23:59' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered 'Day 138' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[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 (0e2f00a6ea3c005e)', Time: '2021-01-02T00:32:55', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'b3283006-a289-4739-b143-5b3a8ed9e91c' | System | 02 Jan 2021 05:33:13 |
| User entered 'No (N)' | System | 02 Jan 2021 05:33:13 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

Have you been exposed to someone with 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 (0e2f00a6ea3c005e)', Time: '2021-01-02T00:33:02', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'b3283006-a289-4739-b143-5b3a8ed9e91c' | System | 02 Jan 2021 05:33:13 |
| User entered 'No (N)' | System | 02 Jan 2021 05:33:13 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2021-01-02T00:33:07', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'b3283006-a289-4739-b143-5b3a8ed9e91c' | System | 02 Jan 2021 05:33:13 |
| User entered '02 Jan 2021 00:33:07' | System | 02 Jan 2021 05:33:13 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '02 Jan 2021 00:01' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '06 Jan 2021 23:59' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered 'Day 145' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[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 (0e2f00a6ea3c005e)', Time: '2021-01-11T00:16:21', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '8b211618-2d72-4034-b77b-e45da8bc1e39' | System | 11 Jan 2021 05:16:35 |
| User entered 'No (N)' | System | 11 Jan 2021 05:16:35 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

Have you been exposed to someone with 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 (0e2f00a6ea3c005e)', Time: '2021-01-11T00:16:26', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '8b211618-2d72-4034-b77b-e45da8bc1e39' | System | 11 Jan 2021 05:16:35 |
| User entered 'No (N)' | System | 11 Jan 2021 05:16:35 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2021-01-11T00:16:31', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '8b211618-2d72-4034-b77b-e45da8bc1e39' | System | 11 Jan 2021 05:16:35 |
| User entered '11 Jan 2021 00:16:31' | System | 11 Jan 2021 05:16:35 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '09 Jan 2021 00:01' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '13 Jan 2021 23:59' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered 'Day 152' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[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 (0e2f00a6ea3c005e)', Time: '2021-01-16T00:12:53', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '40510267-5c3a-4c3c-b1b8-1dc721f021c7' | System | 16 Jan 2021 05:13:13 |
| User entered 'No (N)' | System | 16 Jan 2021 05:13:13 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

Have you been exposed to someone with 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 (0e2f00a6ea3c005e)', Time: '2021-01-16T00:13:00', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '40510267-5c3a-4c3c-b1b8-1dc721f021c7' | System | 16 Jan 2021 05:13:13 |
| User entered 'No (N)' | System | 16 Jan 2021 05:13:13 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2021-01-16T00:13:06', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '40510267-5c3a-4c3c-b1b8-1dc721f021c7' | System | 16 Jan 2021 05:13:13 |
| User entered '16 Jan 2021 00:13:06' | System | 16 Jan 2021 05:13:13 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '16 Jan 2021 00:01' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '20 Jan 2021 23:59' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered 'Day 159' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[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 (0e2f00a6ea3c005e)', Time: '2021-01-23T00:02:00', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '0b1ec58b-045e-4e88-aa21-048e86177402' | System | 23 Jan 2021 05:02:52 |
| User entered 'No (N)' | System | 23 Jan 2021 05:02:52 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

Have you been exposed to someone with 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 (0e2f00a6ea3c005e)', Time: '2021-01-23T00:02:05', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '0b1ec58b-045e-4e88-aa21-048e86177402' | System | 23 Jan 2021 05:02:52 |
| User entered 'No (N)' | System | 23 Jan 2021 05:02:52 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2021-01-23T00:02:09', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '0b1ec58b-045e-4e88-aa21-048e86177402' | System | 23 Jan 2021 05:02:52 |
| User entered '23 Jan 2021 00:02:09' | System | 23 Jan 2021 05:02:52 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '23 Jan 2021 00:01' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '27 Jan 2021 23:59' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered 'Day 166' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[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 (0e2f00a6ea3c005e)', Time: '2021-01-30T04:37:25', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '9171562c-daf8-4c44-8561-e2e374734b0d' | System | 30 Jan 2021 09:37:43 |
| User entered 'No (N)' | System | 30 Jan 2021 09:37:43 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

Have you been exposed to someone with 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 (0e2f00a6ea3c005e)', Time: '2021-01-30T04:37:32', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '9171562c-daf8-4c44-8561-e2e374734b0d' | System | 30 Jan 2021 09:37:43 |
| User entered 'No (N)' | System | 30 Jan 2021 09:37:43 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2021-01-30T04:37:39', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '9171562c-daf8-4c44-8561-e2e374734b0d' User entered '30 Jan 2021 04:37:39' | System | 30 Jan 2021 09:37:43 |
| | System | 30 Jan 2021 09:37:43 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '30 Jan 2021 00:01' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '03 Feb 2021 23:59' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered 'Day 173' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[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 (0e2f00a6ea3c005e)', Time: '2021-02-06T00:02:15', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'db039949-2f5b-4980-a0ac-129dab0e69b8' | System | 06 Feb 2021 05:03:17 |
| User entered 'No (N)' | System | 06 Feb 2021 05:03:17 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

Have you been exposed to someone with 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 (0e2f00a6ea3c005e)', Time: '2021-02-06T00:02:19', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'db039949-2f5b-4980-a0ac-129dab0e69b8' | System | 06 Feb 2021 05:03:17 |
| User entered 'No (N)' | System | 06 Feb 2021 05:03:17 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2021-02-06T00:02:24', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'db039949-2f5b-4980-a0ac-129dab0e69b8' | System | 06 Feb 2021 05:03:17 |
| User entered '06 Feb 2021 00:02:24' | System | 06 Feb 2021 05:03:17 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '06 Feb 2021 00:01' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '10 Feb 2021 23:59' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered 'Day 180' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[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 (0e2f00a6ea3c005e)', Time: '2021-02-15T17:48:47', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '9a9f1eef-7c7f-497f-aab5-6cf1f9292ac6' | System | 15 Feb 2021 22:49:01 |
| User entered 'No (N)' | System | 15 Feb 2021 22:49:01 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Have you been exposed to someone with 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 (0e2f00a6ea3c005e)', Time: '2021-02-15T17:48:51', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '9a9f1eef-7c7f-497f-aab5-6cf1f9292ac6' | System | 15 Feb 2021 22:49:01 |
| User entered 'No (N)' | System | 15 Feb 2021 22:49:01 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2021-02-15T17:48:56', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '9a9f1eef-7c7f-497f-aab5-6cf1f9292ac6' User entered '15 Feb 2021 17:48:56' | System | 15 Feb 2021 22:49:01 |
| | System | 15 Feb 2021 22:49:01 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '13 Feb 2021 00:01' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '17 Feb 2021 23:59' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered 'Day 187' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[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 (0e2f00a6ea3c005e)', Time: '2021-02-20T11:35:00', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '304408c2-64c8-487a-9050-b86c2aac5476' | System | 20 Feb 2021 16:35:14 |
| User entered 'No (N)' | System | 20 Feb 2021 16:35:14 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Have you been exposed to someone with 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 (0e2f00a6ea3c005e)', Time: '2021-02-20T11:35:04', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '304408c2-64c8-487a-9050-b86c2aac5476' | System | 20 Feb 2021 16:35:14 |
| User entered 'No (N)' | System | 20 Feb 2021 16:35:14 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0e2f00a6ea3c005e)', Time: '2021-02-20T11:35:09', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '304408c2-64c8-487a-9050-b86c2aac5476' | System | 20 Feb 2021 16:35:14 |
| User entered '20 Feb 2021 11:35:09' | System | 20 Feb 2021 16:35:14 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '20 Feb 2021 00:01' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '24 Feb 2021 23:59' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered 'Day 194' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[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 (e6d9b871295187b7)', Time: '2021-02-28T10:20:55-05:00', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'be6b1211-081a-4f72-8626-cbdaeb49f2a0' | System | 28 Feb 2021 15:21:08 |
| User entered 'No (N)' | System | 28 Feb 2021 15:21:08 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

Have you been exposed to someone with 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 (e6d9b871295187b7)', Time: '2021-02-28T10:20:59-05:00', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'be6b1211-081a-4f72-8626-cbdaeb49f2a0' | System | 28 Feb 2021 15:21:08 |
| User entered 'No (N)' | System | 28 Feb 2021 15:21:08 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e6d9b871295187b7)', Time: '2021-02-28T10:21:03-05:00', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'be6b1211-081a-4f72-8626-cbdaeb49f2a0' | System | 28 Feb 2021 15:21:08 |
| User entered '28 Feb 2021 10:21:03' | System | 28 Feb 2021 15:21:08 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '27 Feb 2021 00:01' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '03 Mar 2021 23:59' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered 'Day 201' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[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 (e6d9b871295187b7)', Time: '2021-03-06T03:03:21-05:00', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'f2686891-4d1c-4e70-b82e-3cc0b031fc30' | System | 06 Mar 2021 08:03:36 |
| User entered 'No (N)' | System | 06 Mar 2021 08:03:36 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

Have you been exposed to someone with 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 (e6d9b871295187b7)', Time: '2021-03-06T03:03:26-05:00', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'f2686891-4d1c-4e70-b82e-3cc0b031fc30' | System | 06 Mar 2021 08:03:36 |
| User entered 'No (N)' | System | 06 Mar 2021 08:03:36 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e6d9b871295187b7)', Time: '2021-03-06T03:03:31-05:00', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'f2686891-4d1c-4e70-b82e-3cc0b031fc30' User entered '06 Mar 2021 03:03:31' | System | 06 Mar 2021 08:03:36 |
| | System | 06 Mar 2021 08:03:36 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '06 Mar 2021 00:01' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '10 Mar 2021 23:59' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered 'Day 208' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[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 (e6d9b871295187b7)', Time: '2021-03-16T11:10:27-04:00', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '196450c6-2ddc-4740-8b63-a7293b8c5d78' | System | 16 Mar 2021 15:10:43 |
| User entered 'No (N)' | System | 16 Mar 2021 15:10:43 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

Have you been exposed to someone with 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 (e6d9b871295187b7)', Time: '2021-03-16T11:10:31-04:00', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '196450c6-2ddc-4740-8b63-a7293b8c5d78' | System | 16 Mar 2021 15:10:43 |
| User entered 'No (N)' | System | 16 Mar 2021 15:10:43 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e6d9b871295187b7)', Time: '2021-03-16T11:10:35-04:00', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '196450c6-2ddc-4740-8b63-a7293b8c5d78' | System | 16 Mar 2021 15:10:43 |
| User entered '16 Mar 2021 11:10:35' | System | 16 Mar 2021 15:10:43 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '13 Mar 2021 00:01' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '17 Mar 2021 23:59' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered 'Day 215' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[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 (e6d9b871295187b7)', Time: '2021-03-21T09:04:43-04:00', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '8bfb7fb3-94b5-4b51-a6db-ccc5f38eb73' | System | 21 Mar 2021 13:04:53 |
| User entered 'No (N)' | System | 21 Mar 2021 13:04:53 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

Have you been exposed to someone with 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 (e6d9b871295187b7)', Time: '2021-03-21T09:04:47-04:00', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '8bfb7fb3-94b5-4b51-a6db-ccc5f38eb73' | System | 21 Mar 2021 13:04:53 |
| User entered 'No (N)' | System | 21 Mar 2021 13:04:53 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e6d9b871295187b7)', Time: '2021-03-21T09:04:50-04:00', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '8bfb7fb3-94b5-4b51-a6db-ccc5f38eb73' | System | 21 Mar 2021 13:04:53 |
| User entered '21 Mar 2021 09:04:50' | System | 21 Mar 2021 13:04:53 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '20 Mar 2021 00:01' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '24 Mar 2021 23:59' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered 'Day 222' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[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 (e6d9b871295187b7)', Time: '2021-03-29T02:04:04-04:00', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '3e68981e-c141-4f3c-bbb4-d7cb1f50efe4' | System | 29 Mar 2021 06:04:19 |
| User entered 'No (N)' | System | 29 Mar 2021 06:04:19 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

Have you been exposed to someone with 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 (e6d9b871295187b7)', Time: '2021-03-29T02:04:09-04:00', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '3e68981e-c141-4f3c-bbb4-d7cb1f50efe4' | System | 29 Mar 2021 06:04:19 |
| User entered 'No (N)' | System | 29 Mar 2021 06:04:19 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e6d9b871295187b7)', Time: '2021-03-29T02:04:15-04:00', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '3e68981e-c141-4f3c-bbb4-d7cb1f50efe4' User entered '29 Mar 2021 02:04:15' | System | 29 Mar 2021 06:04:19 |
| | System | 29 Mar 2021 06:04:19 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '27 Mar 2021 00:01' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '31 Mar 2021 23:59' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered 'Day 229' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[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 (e6d9b871295187b7)', Time: '2021-04-04T00:30:35-04:00', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'db9ef8b0-da6f-4417-8bf8-fcf5c230e0c3' | System | 04 Apr 2021 04:31:04 |
| User entered 'No (N)' | System | 04 Apr 2021 04:31:04 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

Have you been exposed to someone with 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 (e6d9b871295187b7)', Time: '2021-04-04T00:30:45-04:00', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'db9ef8b0-da6f-4417-8bf8-fcf5c230e0c3' | System | 04 Apr 2021 04:31:04 |
| User entered 'No (N)' | System | 04 Apr 2021 04:31:04 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e6d9b871295187b7)', Time: '2021-04-04T00:31:00-04:00', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'db9ef8b0-da6f-4417-8bf8-fcf5c230e0c3' | System | 04 Apr 2021 04:31:04 |
| User entered '04 Apr 2021 00:31:00' | System | 04 Apr 2021 04:31:04 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '03 Apr 2021 00:01' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '07 Apr 2021 23:59' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered 'Day 236' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[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 (e6d9b871295187b7)', Time: '2021-04-11T12:29:27-04:00', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'ce5f1f75-9760-45b5-bec1-4630cb392ed9' User entered 'No (N)' | System | 11 Apr 2021 16:29:42 |
| | System | 11 Apr 2021 16:29:42 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

Have you been exposed to someone with 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 (e6d9b871295187b7)', Time: '2021-04-11T12:29:34-04:00', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'ce5f1f75-9760-45b5-bec1-4630cb392ed9' | System | 11 Apr 2021 16:29:42 |
| User entered 'No (N)' | System | 11 Apr 2021 16:29:42 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e6d9b871295187b7)', Time: '2021-04-11T12:29:38-04:00', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'ce5f1f75-9760-45b5-bec1-4630cb392ed9' | System | 11 Apr 2021 16:29:42 |
| User entered '11 Apr 2021 12:29:38' | System | 11 Apr 2021 16:29:42 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '10 Apr 2021 00:01' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '14 Apr 2021 23:59' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered 'Day 243' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[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 (e6d9b871295187b7)', Time: '2021-04-18T17:15:39-04:00', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '11c22e53-3b13-4ec0-a5a3-5a8a3e847693' | System | 18 Apr 2021 21:16:14 |
| User entered 'No (N)' | System | 18 Apr 2021 21:16:14 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

Have you been exposed to someone with 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 (e6d9b871295187b7)', Time: '2021-04-18T17:15:48-04:00', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '11c22e53-3b13-4ec0-a5a3-5a8a3e847693' | System | 18 Apr 2021 21:16:14 |
| User entered 'No (N)' | System | 18 Apr 2021 21:16:14 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e6d9b871295187b7)', Time: '2021-04-18T17:15:53-04:00', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: '11c22e53-3b13-4ec0-a5a3-5a8a3e847693' | System | 18 Apr 2021 21:16:14 |
| User entered '18 Apr 2021 17:15:53' | System | 18 Apr 2021 21:16:14 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '17 Apr 2021 00:01' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '21 Apr 2021 23:59' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered 'Day 250' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[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 (e6d9b871295187b7)', Time: '2021-04-24T04:40:52-04:00', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'b1ffd365-9cd8-4a5a-b219-1e22e631abc6' | System | 24 Apr 2021 08:41:12 |
| User entered 'No (N)' | System | 24 Apr 2021 08:41:12 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

Have you been exposed to someone with 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 (e6d9b871295187b7)', Time: '2021-04-24T04:41:03-04:00', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'b1ffd365-9cd8-4a5a-b219-1e22e631abc6' | System | 24 Apr 2021 08:41:12 |
| User entered 'No (N)' | System | 24 Apr 2021 08:41:12 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e6d9b871295187b7)', Time: '2021-04-24T04:41:08-04:00', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'b1ffd365-9cd8-4a5a-b219-1e22e631abc6' | System | 24 Apr 2021 08:41:12 |
| User entered '24 Apr 2021 04:41:08' | System | 24 Apr 2021 08:41:12 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '24 Apr 2021 00:01' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '28 Apr 2021 23:59' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered 'Day 257' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '01 May 2021 00:01' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '05 May 2021 23:59' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered 'Day 264' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '08 May 2021 00:01' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '12 May 2021 23:59' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered 'Day 271' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '15 May 2021 00:01' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '19 May 2021 23:59' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered 'Day 278' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '22 May 2021 00:01' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '26 May 2021 23:59' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered 'Day 285' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '29 May 2021 00:01' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '02 Jun 2021 23:59' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered 'Day 292' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '05 Jun 2021 00:01' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '09 Jun 2021 23:59' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered 'Day 299' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '12 Jun 2021 00:01' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '16 Jun 2021 23:59' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered 'Day 306' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '19 Jun 2021 00:01' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '23 Jun 2021 23:59' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered 'Day 313' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '26 Jun 2021 00:01' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '30 Jun 2021 23:59' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered 'Day 320' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '03 Jul 2021 00:01' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '07 Jul 2021 23:59' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered 'Day 327' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '10 Jul 2021 00:01' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '14 Jul 2021 23:59' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered 'Day 334' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '17 Jul 2021 00:01' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '21 Jul 2021 23:59' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered 'Day 341' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '24 Jul 2021 00:01' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '28 Jul 2021 23:59' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered 'Day 348' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '31 Jul 2021 00:01' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '04 Aug 2021 23:59' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered 'Day 355' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '07 Aug 2021 00:01' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '11 Aug 2021 23:59' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered 'Day 362' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '14 Aug 2021 00:01' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '18 Aug 2021 23:59' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered 'Day 369' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '21 Aug 2021 00:01' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '25 Aug 2021 23:59' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered 'Day 376' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '28 Aug 2021 00:01' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '01 Sep 2021 23:59' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered 'Day 383' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '04 Sep 2021 00:01' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '08 Sep 2021 23:59' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered 'Day 390' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '11 Sep 2021 00:01' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '15 Sep 2021 23:59' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered 'Day 397' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '18 Sep 2021 00:01' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '22 Sep 2021 23:59' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered 'Day 404' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '25 Sep 2021 00:01' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '29 Sep 2021 23:59' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered 'Day 411' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '02 Oct 2021 00:01' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '06 Oct 2021 23:59' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered 'Day 418' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '09 Oct 2021 00:01' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '13 Oct 2021 23:59' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered 'Day 425' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '16 Oct 2021 00:01' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '20 Oct 2021 23:59' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered 'Day 432' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '23 Oct 2021 00:01' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '27 Oct 2021 23:59' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered 'Day 439' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '30 Oct 2021 00:01' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '03 Nov 2021 23:59' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered 'Day 446' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '06 Nov 2021 00:01' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '10 Nov 2021 23:59' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered 'Day 453' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '13 Nov 2021 00:01' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '17 Nov 2021 23:59' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered 'Day 460' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '20 Nov 2021 00:01' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '24 Nov 2021 23:59' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered 'Day 467' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '27 Nov 2021 00:01' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '01 Dec 2021 23:59' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered 'Day 474' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '04 Dec 2021 00:01' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '08 Dec 2021 23:59' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered 'Day 481' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '11 Dec 2021 00:01' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '15 Dec 2021 23:59' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered 'Day 488' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '18 Dec 2021 00:01' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '22 Dec 2021 23:59' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered 'Day 495' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '25 Dec 2021 00:01' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '29 Dec 2021 23:59' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered 'Day 502' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '01 Jan 2022 00:01' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '05 Jan 2022 23:59' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered 'Day 509' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '08 Jan 2022 00:01' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '12 Jan 2022 23:59' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered 'Day 516' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '15 Jan 2022 00:01' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '19 Jan 2022 23:59' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered 'Day 523' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '22 Jan 2022 00:01' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '26 Jan 2022 23:59' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered 'Day 530' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '29 Jan 2022 00:01' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '02 Feb 2022 23:59' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered 'Day 537' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '05 Feb 2022 00:01' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '09 Feb 2022 23:59' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered 'Day 544' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '12 Feb 2022 00:01' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '16 Feb 2022 23:59' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered 'Day 551' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '19 Feb 2022 00:01' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '23 Feb 2022 23:59' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered 'Day 558' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '26 Feb 2022 00:01' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '02 Mar 2022 23:59' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered 'Day 565' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '05 Mar 2022 00:01' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '09 Mar 2022 23:59' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered 'Day 572' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '12 Mar 2022 00:01' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '16 Mar 2022 23:59' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered 'Day 579' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '19 Mar 2022 00:01' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '23 Mar 2022 23:59' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered 'Day 586' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '26 Mar 2022 00:01' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '30 Mar 2022 23:59' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered 'Day 593' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '02 Apr 2022 00:01' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '06 Apr 2022 23:59' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered 'Day 600' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '09 Apr 2022 00:01' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '13 Apr 2022 23:59' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered 'Day 607' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '16 Apr 2022 00:01' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '20 Apr 2022 23:59' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered 'Day 614' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '23 Apr 2022 00:01' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '27 Apr 2022 23:59' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered 'Day 621' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '30 Apr 2022 00:01' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '04 May 2022 23:59' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered 'Day 628' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '07 May 2022 00:01' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '11 May 2022 23:59' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered 'Day 635' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '14 May 2022 00:01' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '18 May 2022 23:59' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered 'Day 642' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '21 May 2022 00:01' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '25 May 2022 23:59' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered 'Day 649' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '28 May 2022 00:01' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '01 Jun 2022 23:59' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered 'Day 656' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '04 Jun 2022 00:01' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '08 Jun 2022 23:59' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered 'Day 663' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '11 Jun 2022 00:01' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '15 Jun 2022 23:59' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered 'Day 670' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '18 Jun 2022 00:01' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '22 Jun 2022 23:59' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered 'Day 677' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '25 Jun 2022 00:01' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '29 Jun 2022 23:59' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered 'Day 684' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '02 Jul 2022 00:01' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '06 Jul 2022 23:59' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered 'Day 691' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '09 Jul 2022 00:01' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '13 Jul 2022 23:59' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered 'Day 698' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '16 Jul 2022 00:01' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '20 Jul 2022 23:59' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered 'Day 705' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '23 Jul 2022 00:01' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '27 Jul 2022 23:59' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered 'Day 712' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '30 Jul 2022 00:01' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '03 Aug 2022 23:59' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered 'Day 719' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '06 Aug 2022 00:01' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '10 Aug 2022 23:59' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered 'Day 726' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '13 Aug 2022 00:01' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '17 Aug 2022 23:59' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered 'Day 733' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '20 Aug 2022 00:01' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '24 Aug 2022 23:59' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered 'Day 740' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '27 Aug 2022 00:01' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '31 Aug 2022 23:59' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered 'Day 747' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '03 Sep 2022 00:01' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '07 Sep 2022 23:59' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered 'Day 754' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '10 Sep 2022 00:01' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '14 Sep 2022 23:59' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered 'Day 761' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '17 Sep 2022 00:01' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '21 Sep 2022 23:59' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered 'Day 768' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '24 Sep 2022 00:01' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '28 Sep 2022 23:59' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered 'Day 775' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '01 Oct 2022 00:01' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '05 Oct 2022 23:59' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered 'Day 782' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '08 Oct 2022 00:01' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '12 Oct 2022 23:59' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered 'Day 789' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '15 Oct 2022 00:01' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '19 Oct 2022 23:59' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered 'Day 796' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '22 Oct 2022 00:01' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:49:23 |
| Amendment Manager: User entered '26 Oct 2022 23:59' | System | 19 Nov 2020 23:49:23 |

US3722338

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:26:23

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e6d9b871295187b7)', Time: '2021-02-28T10:20:37-05:00', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'fada1ed1-fc33-4fbb-9289-71ec435140d2' | System | 28 Feb 2021 15:20:45 |
| User entered 'No (N)' | System | 28 Feb 2021 15:20:45 |

US3722338

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:26:23

[Date & Time of Submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 03:59:08 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e6d9b871295187b7)', Time: '2021-02-28T10:20:41-05:00', User OID: 'PatientReportedOutcome (US3722338)', ODM File OID: 'fada1ed1-fc33-4fbb-9289-71ec435140d2' | System | 28 Feb 2021 15:20:45 |
| User entered '28 Feb 2021 10:20:41' | System | 28 Feb 2021 15:20:45 |

US3722338

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:26:23

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered 'No (N)' | Marlee Smith (b) (4) | 11 Feb 2021 18:41:37 |

US3722338

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:26:23

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered empty. | Marlee Smith (b) (4) | 11 Feb 2021 18:41:37 |

US3722338

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:26:23

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered empty. | Marlee Smith (b) (4) | 11 Feb 2021 18:41:37 |

US3722338

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:26:23

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered empty. | Marlee Smith (b) (4) | 11 Feb 2021 18:41:37 |

US3722338

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:26:23

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 25 Feb 2021 17:47:46 |
| User entered 'Yes (Y)' | Marlee Smith (b) (4) | 11 Feb 2021 18:41:40 |

US3722338

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:26:23

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:54:37 |
| User entered 'I' | System | 11 Feb 2021 18:41:40 |

US3722338

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:26:23

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 13:27:26 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered 'No (N)' | Marlee Smith (b) (4) | 11 Feb 2021 18:41:48 |

US3722338

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:26:23

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 13:27:26 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered empty. | Marlee Smith (b) (4) | 11 Feb 2021 18:41:48 |

US3722338

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:26:23

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 13:27:26 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered empty. | Marlee Smith (b) (4) | 11 Feb 2021 18:41:48 |

US3722338

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:26:23

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 13:27:26 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered empty. | Marlee Smith (b) (4) | 11 Feb 2021 18:41:48 |

US3722338

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:26:23

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 13:27:26 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered 'Yes (Y)' | Marlee Smith (b) (4) | 11 Feb 2021 18:41:51 |

US3722338

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:26:23

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 13:27:26 |
| User entered 'I' | System | 11 Feb 2021 18:41:51 |

US3722338

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:26:23

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 08:32:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered 'No (N)' | Marlee Smith (b) (4) | 11 Feb 2021 18:42:04 |

US3722338

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:26:23

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 08:32:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered empty. | Marlee Smith (b) (4) | 11 Feb 2021 18:42:04 |

US3722338

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:26:23

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 08:32:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered empty. | Marlee Smith (b) (4) | 11 Feb 2021 18:42:04 |

US3722338

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:26:23

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 08:32:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered empty. | Marlee Smith (b) (4) | 11 Feb 2021 18:42:04 |

US3722338

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:26:23

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 08:32:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered 'Yes (Y)' | Marlee Smith (b) (4) | 11 Feb 2021 18:42:08 |

US3722338

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:26:23

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 08:32:01 |
| User entered 'I' | System | 11 Feb 2021 18:42:08 |

US3722338

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:26:23

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 20:11:07 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered 'Yes (Y)' | Marlee Smith (b) (4) | 11 Feb 2021 18:42:16 |

US3722338

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:26:23

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 20:11:07 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered '11 Feb 2021' | Marlee Smith (b) (4) | 11 Feb 2021 18:42:16 |

US3722338

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:26:23

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 20:11:07 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered 'Contact Made (CONTACT MADE)' | Marlee Smith (b) (4) | 11 Feb 2021 18:42:16 |

US3722338

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:26:23

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 20:11:07 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered empty. | Marlee Smith (b) (4) | 11 Feb 2021 18:42:16 |

US3722338

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:26:23

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 20:11:07 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered 'Yes (Y)' | Marlee Smith (b) (4) | 11 Feb 2021 18:42:20 |

US3722338

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:26:23

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 20:11:07 |
| User entered 'I' | System | 11 Feb 2021 18:42:20 |

US3722338

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:26:23

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered 'Yes (Y)' | Marlee Smith (b) (4) | 08 Mar 2021 21:52:36 |

US3722338

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered '8 Mar 2021' | Marlee Smith (b) (4) | 08 Mar 2021 21:52:36 |

US3722338

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|--------------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered 'Clinic (Clinic)' | Marlee Smith (b) (4) | 08 Mar 2021 21:52:36 |

US3722338

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:26:23

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User entered 'VISIT4' | System | 08 Mar 2021 21:52:36 |

US3722338

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:26:23

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:11:10 |
| | | |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 10:07:46 |
| | | |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| | (b) (4) | |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| | | |
| User entered 'Yes (Y)' | Marlee Smith (b) (4) | 30 Mar 2021 18:01:12 |
| | (b) (4) | |

US3722338

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:26:23

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:11:10 |
| | | |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 10:07:46 |
| | | |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| | (b) (4) | |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| | | |
| User entered '8 Mar 2021' | Marlee Smith (b) (4) | 30 Mar 2021 18:01:12 |
| | (b) (4) | |

US3722338

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:11:10 |
| | | |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 10:07:46 |
| | | |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| | (b) (4) | |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| | | |
| User entered '13:59' | Marlee Smith (b) (4) | 30 Mar 2021 18:01:12 |
| | (b) (4) | |

US3722338

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:11:10 |
| | | |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 10:07:46 |
| | | |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| | | |
| User entered '8 Mar 2021 13:59' | System | 30 Mar 2021 18:01:12 |

US3722338

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:26:23

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:11:10 |
| | | |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 10:07:46 |
| | | |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| | (b) (4) | |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| | | |
| User entered '97.8' F | Marlee Smith (b) (4) | 30 Mar 2021 18:01:12 |
| | (b) (4) | |

US3722338

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:26:23

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:11:10 |
| | | |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 10:07:46 |
| | | |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| | (b) (4) | |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| | | |
| User entered 'Oral (Oral)' | Marlee Smith (b) (4) | 30 Mar 2021 18:01:12 |
| | (b) (4) | |

US3722338

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:26:23

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:11:10 |
| | | |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 10:07:46 |
| | | |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| | (b) (4) | |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| | | |
| User entered empty. | Marlee Smith (b) (4) | 30 Mar 2021 18:01:12 |
| | (b) (4) | |

US3722338

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:26:23

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:11:10 |
| | | |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 10:07:46 |
| | | |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| | (b) (4) | |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| | | |
| User entered '80' | Marlee Smith (b) (4) | 30 Mar 2021 18:01:12 |
| | (b) (4) | |

US3722338

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:26:23

[Pulse units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:11:10 |
| | | |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 10:07:46 |
| | | |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| | | |
| User entered 'bpm' | System | 30 Mar 2021 18:01:12 |

US3722338

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:11:10 |
| | | |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 10:07:46 |
| | | |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| | (b) (4) | |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| | | |
| User entered '17' | Marlee Smith (b) (4) | 30 Mar 2021 18:01:12 |
| | (b) (4) | |

US3722338

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:26:23

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:11:10 |
| | | |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 10:07:46 |
| | | |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| | | |
| User entered 'breaths/min' | System | 30 Mar 2021 18:01:12 |

US3722338

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:11:10 |
| | | |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 10:07:46 |
| | | |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| | (b) (4) | |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| | | |
| User entered '120' | Marlee Smith (b) (4) | 30 Mar 2021 18:01:12 |
| | (b) (4) | |

US3722338

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:26:23

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:11:10 |
| | | |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 10:07:46 |
| | | |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| | | |
| User entered 'mmHg' | System | 30 Mar 2021 18:01:12 |

US3722338

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:26:23

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:11:10 |
| | | |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 10:07:46 |
| | | |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| | (b) (4) | |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| | | |
| User entered '66' | Marlee Smith (b) (4) | 30 Mar 2021 18:01:12 |
| | (b) (4) | |

US3722338

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:26:23

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:11:10 |
| | | |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 10:07:46 |
| | | |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| | | |
| User entered 'mmHg' | System | 30 Mar 2021 18:01:12 |

US3722338

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:26:23

[Height \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:11:10 |
| | | |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 10:07:46 |
| | | |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| | | |

US3722338

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:26:23

Weight (derived)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 22:11:10 |
| | | |
| Data hard unlocked. | (b) (4), (b) (6) | 29 Apr 2021 10:07:46 |
| | | |
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| | | |

US3722338

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:26:23

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered 'No (N)' | Marlee Smith (b) (4) | 08 Mar 2021 21:52:40 |

US3722338

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:26:23

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered empty. | (b) (4) Marlee Smith (b) (4) | 08 Mar 2021 21:52:40 |

US3722338

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:26:23

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered 'Yes (Y)' | (b) (4) Marlee Smith (b) (4) | 08 Mar 2021 21:52:50 |

US3722338

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:26:23

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered '8 Mar 2021' | (b) (4) Marlee Smith (b) (4) | 08 Mar 2021 21:52:50 |

US3722338

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:26:23

Collection time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered '14:32' | (b) (4) Marlee Smith (b) (4) | 08 Mar 2021 21:52:50 |

US3722338

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:26:23

Collection date and time (derived)

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User entered '8 Mar 2021 14:32' | System | 08 Mar 2021 21:52:50 |

US3722338

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:26:23

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 09 Mar 2021 11:33:22 |
| User entered 'Yes (Y)' | (b) (4) Marlee Smith (b) (4) | 08 Mar 2021 21:52:54 |

US3722338

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:26:23

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 04:12:01 |
| User entered 'I' | System | 08 Mar 2021 21:52:54 |

US3722338

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:26:23

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Taylor Wilson (b) (4) | 12 Apr 2021 15:04:38 |
| | (b) (4) | |

US3722338

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:26:23

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| | (b) (4) | |
| User entered '12 Apr 2021' | Taylor Wilson (b) (4) | 12 Apr 2021 15:04:38 |
| | (b) (4) | |

US3722338

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:26:23

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| | (b) (4) | |
| User entered 'Contact Made (CONTACT MADE)' | Taylor Wilson (b) (4) | 12 Apr 2021 15:04:38 |
| | (b) (4) | |

US3722338

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:26:23

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| | (b) (4) | |
| User entered empty. | Taylor Wilson (b) (4) | 12 Apr 2021 15:04:38 |
| | (b) (4) | |

US3722338

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:26:23

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Taylor Wilson (b) (4) | 12 Apr 2021 15:04:45 |
| | (b) (4) | |

US3722338

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:26:23

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 12 Apr 2021 15:04:45 |

US3722338

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

Form: Visit Date

Generated On: 10 Jun 2021 09:26:23

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:28:55 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered 'Yes (Y)' | (b) (4) Marlee Smith (b) (4) | 11 Jan 2021 19:43:14 |

US3722338

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

Form: Visit Date

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:28:55 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered '11 Jan 2021' | (b) (4) Marlee Smith (b) (4) (b) (4) | 11 Jan 2021 19:43:14 |

US3722338

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

Form: Visit Date

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|--------------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:28:55 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered 'Clinic (Clinic)' | Marlee Smith (b) (4) | 11 Jan 2021 19:43:14 |

US3722338

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

Form: Visit Date

Generated On: 10 Jun 2021 09:26:23

[Folder OID](#)

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:28:55 |
| User entered 'UNBLND_DECIDE' | System | 11 Jan 2021 19:43:14 |

US3722338

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

Form: Unblinding

Generated On: 10 Jun 2021 09:26:23

Date of updated informed consent (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:28:55 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered '11 Jan 2021' | (b) (4) Marlee Smith (b) (4) | 11 Jan 2021 19:43:25 |

US3722338

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

Form: Unblinding

Generated On: 10 Jun 2021 09:26:23

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:28:55 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered '0' WR# 5295537 | (b) (4) | 10 Mar 2021 16:55:28 |
| Amendment Manager inserted this DataPoint. | System | 06 Mar 2021 13:17:28 |

US3722338

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

Form: Unblinding

Generated On: 10 Jun 2021 09:26:23

[Was the participant unblinded?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:28:55 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered 'Yes (Y)' | (b) (4) Marlee Smith (b) (4) | 11 Jan 2021 19:43:25 |

US3722338

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

Form: Unblinding

Generated On: 10 Jun 2021 09:26:23

[Under what version of the Protocol was the Participant unblinded?](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:28:55 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User closed query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 26 Apr 2021 15:57:05 |
| Query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'updated' (Site from DM). | Marlee Smith (b) (4) (b) (4) | 22 Apr 2021 13:25:05 |
| User entered 'Amendment 6 or later (Amendment 6 or later)' reason for change: Data Entry Error | Marlee Smith (b) (4) (b) (4) | 22 Apr 2021 13:25:02 |
| User opened query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM). | (b) (4), (b) (6) | 22 Apr 2021 11:01:33 |
| User entered empty. WR# 5295537 | System | 10 Mar 2021 16:55:28 |
| Amendment Manager inserted this DataPoint. | System | 06 Mar 2021 13:17:28 |

US3722338

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

Form: Unblinding

Generated On: 10 Jun 2021 09:26:23

Date of unblinding (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:28:55 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered '11 Jan 2021' | (b) (4) Marlee Smith (b) (4) (b) (4) | 11 Jan 2021 19:43:25 |

US3722338

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

Form: Unblinding

Generated On: 10 Jun 2021 09:26:23

[Participant randomization assignment](#)

| Audit | User | Time (GMT) |
|----------------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:28:55 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered 'Placebo (Placebo)' | (b) (4) Marlee Smith (b) (4) (b) (4) | 11 Jan 2021 19:43:25 |

US3722338

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

Form: Unblinding

Generated On: 10 Jun 2021 09:26:23

[Actual Dose 1](#)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:28:55 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| Amendment Manager: User entered 'Placebo (Placebo)' | (b) (4) | 20 Jan 2021 07:51:56 |
| User entered 'Placebo (Placebo)' | Marlee Smith (b) (4) | 11 Jan 2021 19:43:25 |
| | (b) (4) | |

US3722338

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

Form: Unblinding

Generated On: 10 Jun 2021 09:26:23

[Actual Dose 2](#)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:28:55 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| Amendment Manager: User entered 'Placebo (Placebo)' | (b) (4) | 20 Jan 2021 07:51:56 |
| User entered 'Placebo (Placebo)' | Marlee Smith (b) (4) | 11 Jan 2021 19:43:25 |
| | (b) (4) | |

US3722338

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

Form: Unblinding

Generated On: 10 Jun 2021 09:26:23

[Will participant receive mRNA-1273?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:28:55 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered 'Yes (Y)' | (b) (4) Marlee Smith (b) (4) | 11 Jan 2021 19:43:25 |

US3722338

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

Form: Unblinding

Generated On: 10 Jun 2021 09:26:23

[Placebo Only Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:28:55 |
| User entered '1' | System | 11 Jan 2021 19:43:25 |

US3722338

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

Form: Unblinding

Generated On: 10 Jun 2021 09:26:23

[Continuing with mRNA-1273](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:28:55 |
| User entered 'I' | System | 11 Jan 2021 19:43:25 |

US3722338

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:26:23

[Height](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:28:55 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered empty. | (b) (4) Marlee Smith (b) (4) | 11 Jan 2021 19:44:59 |

US3722338

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:26:23

[Weight](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:28:55 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered empty. | (b) (4) Marlee Smith (b) (4) (b) (4) | 11 Jan 2021 19:44:59 |

US3722338

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:26:23

BMI (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:28:55 |
| User entered empty. | System | 11 Jan 2021 19:44:59 |
| DataPoint set to visible. | System | 11 Jan 2021 19:43:25 |

US3722338

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:26:23

[Height](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:28:55 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered empty. | (b) (4) Marlee Smith (b) (4) | 11 Jan 2021 19:44:59 |

US3722338

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:26:23

[Weight](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:28:55 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered empty. | (b) (4) Marlee Smith (b) (4) | 11 Jan 2021 19:44:59 |

US3722338

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:26:23

BMI (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:28:55 |
| User entered empty. | System | 11 Jan 2021 19:44:59 |
| DataPoint set to visible. | System | 11 Jan 2021 19:43:25 |

US3722338

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:26:23

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:28:55 |
| User accepted default value 'Pre-Dose (PREDOSE)' | Marlee Smith (b) (4) (b) (4) | 11 Jan 2021 19:44:59 |

US3722338

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:26:23

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:28:55 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered 'Yes (Y)' | (b) (4) Marlee Smith (b) (4) | 11 Jan 2021 19:44:59 |

US3722338

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:26:23

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:28:55 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered '11 Jan 2021' | (b) (4) Marlee Smith (b) (4) (b) (4) | 11 Jan 2021 19:44:59 |

US3722338

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:28:55 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered '13:40' | (b) (4) Marlee Smith (b) (4) (b) (4) | 11 Jan 2021 19:44:59 |

US3722338

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:28:55 |
| User entered '11 Jan 2021 13:40' | System | 11 Jan 2021 19:44:59 |

US3722338

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:26:23

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:28:55 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered '98' F | (b) (4) Marlee Smith (b) (4) (b) (4) | 11 Jan 2021 19:44:59 |

US3722338

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:26:23

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:28:55 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered 'Oral (Oral)' | (b) (4) Marlee Smith (b) (4) (b) (4) | 11 Jan 2021 19:44:59 |

US3722338

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:26:23

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:28:55 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered empty. | (b) (4) Marlee Smith (b) (4) (b) (4) | 11 Jan 2021 19:44:59 |

US3722338

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:26:23

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:28:55 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered '76' | (b) (4) Marlee Smith (b) (4) (b) (4) | 11 Jan 2021 19:44:59 |

US3722338

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:26:23

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:28:55 |
| User entered 'bpm' | System | 11 Jan 2021 19:44:59 |

US3722338

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:28:55 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered '16' | (b) (4) Marlee Smith (b) (4) (b) (4) | 11 Jan 2021 19:44:59 |

US3722338

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:26:23

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:28:55 |
| User entered 'breaths/min' | System | 11 Jan 2021 19:44:59 |

US3722338

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:26:23

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:28:55 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered '126' | (b) (4) Marlee Smith (b) (4) | 11 Jan 2021 19:44:59 |

US3722338

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:26:23

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:28:55 |
| User entered 'mmHg' | System | 11 Jan 2021 19:44:59 |

US3722338

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:28:55 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered '70' | (b) (4) Marlee Smith (b) (4) (b) (4) | 11 Jan 2021 19:44:59 |

US3722338

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:26:23

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:28:55 |
| User entered 'mmHg' | System | 11 Jan 2021 19:44:59 |

US3722338

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:26:23

[Height](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:28:55 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered empty. | (b) (4) Marlee Smith (b) (4) | 11 Jan 2021 19:44:59 |

US3722338

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:26:23

[Weight](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:28:55 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered empty. | (b) (4) Marlee Smith (b) (4) | 11 Jan 2021 19:44:59 |

US3722338

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:26:23

BMI (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:28:55 |
| User entered empty. | System | 11 Jan 2021 19:44:59 |
| DataPoint set to visible. | System | 11 Jan 2021 19:43:25 |

US3722338

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:26:23

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:28:55 |
| User accepted default value 'Post-Dose (POSTDOSE)' | Marlee Smith (b) (4) (b) (4) | 11 Jan 2021 19:44:59 |

US3722338

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:26:23

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:28:55 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered 'Yes (Y)' | (b) (4) Marlee Smith (b) (4) | 11 Jan 2021 19:44:59 |

US3722338

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:26:23

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:28:55 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered '11 Jan 2021' | (b) (4) Marlee Smith (b) (4) (b) (4) | 11 Jan 2021 19:44:59 |

US3722338

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:28:55 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered '14:14' | (b) (4) Marlee Smith (b) (4) (b) (4) | 11 Jan 2021 19:44:59 |

US3722338

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:28:55 |
| User entered '11 Jan 2021 14:14' | System | 11 Jan 2021 19:44:59 |

US3722338

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:26:23

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:28:55 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered '97.4' F | (b) (4) Marlee Smith (b) (4) (b) (4) | 11 Jan 2021 19:44:59 |

US3722338

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:26:23

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:28:55 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered 'Oral (Oral)' | (b) (4) Marlee Smith (b) (4) (b) (4) | 11 Jan 2021 19:44:59 |

US3722338

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:26:23

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:28:55 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered empty. | (b) (4) Marlee Smith (b) (4) (b) (4) | 11 Jan 2021 19:44:59 |

US3722338

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:26:23

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:28:55 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered '71' | (b) (4) Marlee Smith (b) (4) (b) (4) | 11 Jan 2021 19:44:59 |

US3722338

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:26:23

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:28:55 |
| User entered 'bpm' | System | 11 Jan 2021 19:44:59 |

US3722338

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:28:55 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered '17' | (b) (4) Marlee Smith (b) (4) (b) (4) | 11 Jan 2021 19:44:59 |

US3722338

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:26:23

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:28:55 |
| User entered 'breaths/min' | System | 11 Jan 2021 19:44:59 |

US3722338

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:26:23

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:28:55 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered '126' | (b) (4) Marlee Smith (b) (4) | 11 Jan 2021 19:44:59 |

US3722338

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:26:23

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:28:55 |
| User entered 'mmHg' | System | 11 Jan 2021 19:44:59 |

US3722338

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:28:55 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered '66' | (b) (4) Marlee Smith (b) (4) (b) (4) | 11 Jan 2021 19:44:59 |

US3722338

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:26:23

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:28:55 |
| User entered 'mmHg' | System | 11 Jan 2021 19:44:59 |

US3722338

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

Form: Physical Examination

Generated On: 10 Jun 2021 09:26:23

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:28:55 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered 'Yes (Y)' | (b) (4) Marlee Smith (b) (4) | 11 Jan 2021 19:45:07 |

US3722338

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

Form: Physical Examination

Generated On: 10 Jun 2021 09:26:23

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:28:55 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered '11 Jan 2021' | (b) (4) Marlee Smith (b) (4) (b) (4) | 11 Jan 2021 19:45:07 |

US3722338

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

Form: Exposure

Generated On: 10 Jun 2021 09:26:23

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:28:55 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered 'Yes (Y)' | (b) (4) Marlee Smith (b) (4) | 11 Jan 2021 19:45:19 |

US3722338

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

Form: Exposure

Generated On: 10 Jun 2021 09:26:23

[If No, reason not given](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:28:55 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered empty. | (b) (4) Marlee Smith (b) (4) | 11 Jan 2021 19:45:19 |

US3722338

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

Form: Exposure

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:28:55 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered empty. | Marlee Smith (b) (4) | 11 Jan 2021 19:45:19 |

US3722338

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

Form: Exposure

Generated On: 10 Jun 2021 09:26:23

[What was the study treatment? \(Unblinded\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:28:55 |
| User entered 'mRNA-1273' | System | 11 Jan 2021 19:45:19 |
| DataPoint set to visible. | System | 11 Jan 2021 19:43:25 |

US3722338

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

Form: Exposure

Generated On: 10 Jun 2021 09:26:23

What was the treatment date? (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:28:55 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered '11 Jan 2021' | Marlee Smith (b) (4) | 11 Jan 2021 19:45:19 |

US3722338

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

Form: Exposure

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:28:55 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered '13:44' | (b) (4) Marlee Smith (b) (4) | 11 Jan 2021 19:45:19 |

US3722338

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

Form: Exposure

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:28:55 |
| User entered '11 Jan 2021 13:44' | System | 11 Jan 2021 19:45:19 |

US3722338

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

Form: Exposure

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|--------------------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:28:55 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered 'Right Arm (RIGHT ARM)' | Marlee Smith (b) (4) | 11 Jan 2021 19:45:19 |

US3722338

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

Form: Exposure

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:28:55 |
| User entered 'ONCE' | System | 11 Jan 2021 19:45:19 |

US3722338

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

Form: Exposure

Generated On: 10 Jun 2021 09:26:23

What was the route of administration for the study treatment?

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:28:55 |
| User entered 'INTRAMUSCULAR' | System | 11 Jan 2021 19:45:19 |

US3722338

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:26:23

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:28:55 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered 'Yes (Y)' | (b) (4) Marlee Smith (b) (4) | 11 Jan 2021 19:43:33 |
| | (b) (4) | |

US3722338

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:26:23

Collection date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:28:55 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered '11 Jan 2021' | (b) (4) Marlee Smith (b) (4) | 11 Jan 2021 19:43:33 |

US3722338

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:26:23

Collection time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:28:55 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered '13:20' | (b) (4) Marlee Smith (b) (4) (b) (4) | 11 Jan 2021 19:43:33 |

US3722338

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:26:23

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:28:55 |
| User entered '11 Jan 2021 13:20' | System | 11 Jan 2021 19:43:33 |

US3722338

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:26:23

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:28:55 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered 'Yes (Y)' | (b) (4) Marlee Smith (b) (4) | 11 Jan 2021 19:43:40 |

US3722338

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:26:23

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:28:55 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered '11 Jan 2021' | (b) (4) Marlee Smith (b) (4) | 11 Jan 2021 19:43:40 |

US3722338

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:26:23

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:28:55 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered '13:22' | (b) (4) | |
| | Marlee Smith (b) (4) | 11 Jan 2021 19:43:40 |
| | (b) (4) | |

US3722338

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:28:55 |
| User entered '11 Jan 2021 13:22' | System | 11 Jan 2021 19:43:40 |

US3722338

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

Form: Continuing

Generated On: 10 Jun 2021 09:26:23

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:28:55 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered 'Yes (Y)' | (b) (4) Marlee Smith (b) (4) | 11 Jan 2021 19:43:47 |

US3722338

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

Form: Continuing

Generated On: 10 Jun 2021 09:26:23

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:28:55 |
| User entered '1' | System | 11 Jan 2021 19:43:47 |

US3722338

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:26:23

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:24:09 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered 'Yes (Y)' | Marlee Smith (b) (4) | 19 Jan 2021 15:32:26 |

US3722338

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:26:23

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:24:09 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered '19 Jan 2021' | Marlee Smith (b) (4) | 19 Jan 2021 15:32:26 |

US3722338

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:26:23

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:24:09 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered 'Contact Made (CONTACT MADE)' | Marlee Smith (b) (4) | 19 Jan 2021 15:32:26 |

US3722338

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:26:23

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:24:09 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered empty. | Marlee Smith (b) (4) | 19 Jan 2021 15:32:26 |

US3722338

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:26:23

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:24:09 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered 'Yes (Y)' | Marlee Smith (b) (4) | 19 Jan 2021 15:32:30 |

US3722338

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:26:23

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:24:09 |
| User entered 'I' | System | 19 Jan 2021 15:32:30 |

US3722338

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:26:23

[OLD29 Placebo Flag](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:24:09 |
| User entered '1' | System | 19 Jan 2021 15:32:30 |
| DataPoint set to visible. | System | 19 Jan 2021 15:32:30 |

US3722338

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:26:23

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 20:13:28 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered 'Yes (Y)' | Marlee Smith (b) (4) | 09 Feb 2021 14:58:07 |

US3722338

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 20:13:28 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered '8 Feb 2021' | Marlee Smith (b) (4) | 09 Feb 2021 14:58:07 |

US3722338

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|--------------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 20:13:28 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered 'Clinic (Clinic)' | Marlee Smith (b) (4) | 09 Feb 2021 14:58:07 |

US3722338

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:26:23

[Folder OID](#)

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 20:13:28 |
| User entered 'OLD29' | System | 09 Feb 2021 14:58:07 |

US3722338

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:26:23

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 20:13:28 |
| User accepted default value 'Pre-Dose (PREDOSE)' | Marlee Smith (b) (4) (b) (4) | 09 Feb 2021 14:59:01 |

US3722338

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:26:23

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 20:13:28 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered 'Yes (Y)' | Marlee Smith (b) (4) | 09 Feb 2021 14:59:01 |

US3722338

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:26:23

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 20:13:28 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered '8 Feb 2021' | (b) (4) Marlee Smith (b) (4) (b) (4) | 09 Feb 2021 14:59:01 |

US3722338

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 20:13:28 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered '15:36' | (b) (4) Marlee Smith (b) (4) | 09 Feb 2021 14:59:01 |

US3722338

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 20:13:28 |
| User entered '8 Feb 2021 15:36' | System | 09 Feb 2021 14:59:01 |

US3722338

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:26:23

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 20:13:28 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered '98' F | Marlee Smith (b) (4) | 09 Feb 2021 14:59:01 |

US3722338

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:26:23

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 20:13:28 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered 'Oral (Oral)' | Marlee Smith (b) (4) | 09 Feb 2021 14:59:01 |

US3722338

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:26:23

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 20:13:28 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered empty. | (b) (4) Marlee Smith (b) (4) | 09 Feb 2021 14:59:01 |

US3722338

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:26:23

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 20:13:28 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered '89' | Marlee Smith (b) (4) | 09 Feb 2021 14:59:01 |

US3722338

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:26:23

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 20:13:28 |
| User entered 'bpm' | System | 09 Feb 2021 14:59:01 |

US3722338

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 20:13:28 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered '15' | (b) (4) Marlee Smith (b) (4) | 09 Feb 2021 14:59:01 |

US3722338

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:26:23

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 20:13:28 |
| User entered 'breaths/min' | System | 09 Feb 2021 14:59:01 |

US3722338

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:26:23

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 20:13:28 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered '114' | Marlee Smith (b) (4) | 09 Feb 2021 14:59:01 |

US3722338

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:26:23

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 20:13:28 |
| User entered 'mmHg' | System | 09 Feb 2021 14:59:01 |

US3722338

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 20:13:28 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered '62' | Marlee Smith (b) (4) | 09 Feb 2021 14:59:01 |

US3722338

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:26:23

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 20:13:28 |
| User entered 'mmHg' | System | 09 Feb 2021 14:59:01 |

US3722338

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:26:23

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 20:13:28 |
| User accepted default value 'Post-Dose (POSTDOSE)' | Marlee Smith (b) (4) (b) (4) | 09 Feb 2021 14:59:01 |

US3722338

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:26:23

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 20:13:28 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered 'Yes (Y)' | (b) (4) Marlee Smith (b) (4) | 09 Feb 2021 14:59:01 |

US3722338

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:26:23

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 20:13:28 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered '8 Feb 2021' | (b) (4) Marlee Smith (b) (4) | 09 Feb 2021 14:59:01 |

US3722338

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 20:13:28 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered '16:17' | (b) (4) Marlee Smith (b) (4) (b) (4) | 09 Feb 2021 14:59:01 |

US3722338

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 20:13:28 |
| User entered '8 Feb 2021 16:17' | System | 09 Feb 2021 14:59:01 |

US3722338

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:26:23

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 20:13:28 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered '98.7' F | Marlee Smith (b) (4) | 09 Feb 2021 14:59:01 |

US3722338

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:26:23

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 20:13:28 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered 'Oral (Oral)' | Marlee Smith (b) (4) | 09 Feb 2021 14:59:01 |

US3722338

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:26:23

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 20:13:28 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered empty. | Marlee Smith (b) (4) | 09 Feb 2021 14:59:01 |

US3722338

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:26:23

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 20:13:28 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered '92' | Marlee Smith (b) (4) | 09 Feb 2021 14:59:01 |

US3722338

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:26:23

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 20:13:28 |
| User entered 'bpm' | System | 09 Feb 2021 14:59:01 |

US3722338

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 20:13:28 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered '17' | Marlee Smith (b) (4) | 09 Feb 2021 14:59:01 |

US3722338

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:26:23

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 20:13:28 |
| User entered 'breaths/min' | System | 09 Feb 2021 14:59:01 |

US3722338

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:26:23

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 20:13:28 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered '121' | Marlee Smith (b) (4) | 09 Feb 2021 14:59:01 |

US3722338

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:26:23

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 20:13:28 |
| User entered 'mmHg' | System | 09 Feb 2021 14:59:01 |

US3722338

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:26:23

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 20:13:28 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered '64' | Marlee Smith (b) (4) | 09 Feb 2021 14:59:01 |

US3722338

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:26:23

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 20:13:28 |
| User entered 'mmHg' | System | 09 Feb 2021 14:59:01 |

US3722338

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:26:23

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 20:13:28 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered 'No (N)' | (b) (4) Marlee Smith (b) (4) | 09 Feb 2021 14:59:05 |

US3722338

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:26:23

Date of examination (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 20:13:28 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered empty. | (b) (4) Marlee Smith (b) (4) | 09 Feb 2021 14:59:05 |

US3722338

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:26:23

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 20:13:28 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered 'Yes (Y)' | Marlee Smith (b) (4) | 09 Feb 2021 14:59:18 |

US3722338

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:26:23

[If No, reason not given](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 20:13:28 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered empty. | Marlee Smith (b) (4) | 09 Feb 2021 14:59:18 |

US3722338

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 20:13:28 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered empty. | Marlee Smith (b) (4) | 09 Feb 2021 14:59:18 |

US3722338

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:26:23

[What was the study treatment? \(Unblinded\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 20:13:28 |
| User entered 'mRNA-1273' | System | 09 Feb 2021 14:59:18 |
| DataPoint set to visible. | System | 19 Jan 2021 15:32:30 |

US3722338

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:26:23

[What was the treatment date? \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 20:13:28 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered '8 Feb 2021' | Marlee Smith (b) (4) | 09 Feb 2021 14:59:18 |

US3722338

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 20:13:28 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered '15:47' | Marlee Smith (b) (4) | 09 Feb 2021 14:59:18 |

US3722338

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 20:13:28 |
| User entered '8 Feb 2021 15:47' | System | 09 Feb 2021 14:59:18 |

US3722338

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|--------------------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 20:13:28 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered 'Right Arm (RIGHT ARM)' | Marlee Smith (b) (4) | 09 Feb 2021 14:59:18 |

US3722338

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 20:13:28 |
| User entered 'ONCE' | System | 09 Feb 2021 14:59:18 |

US3722338

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:26:23

What was the route of administration for the study treatment?

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 20:13:28 |
| User entered 'INTRAMUSCULAR' | System | 09 Feb 2021 14:59:18 |

US3722338

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:26:23

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 20:13:28 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered 'Yes (Y)' | Marlee Smith (b) (4) | 09 Feb 2021 14:59:22 |

US3722338

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:26:23

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 20:13:28 |
| User entered 'I' | System | 09 Feb 2021 14:59:22 |

US3722338

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:26:23

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 12:03:51 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered 'Yes (Y)' | Taylor Wilson (b) (4) | 15 Feb 2021 18:53:13 |

US3722338

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:26:23

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 12:03:51 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered '15 Feb 2021' | Taylor Wilson (b) (4) | 15 Feb 2021 18:53:13 |

US3722338

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:26:23

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 12:03:51 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered 'Contact Made (CONTACT MADE)' | Taylor Wilson (b) (4) | 15 Feb 2021 18:53:13 |

US3722338

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:26:23

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 12:03:51 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered empty. | Taylor Wilson (b) (4) | 15 Feb 2021 18:53:13 |

US3722338

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:26:23

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 12:03:51 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered 'Yes (Y)' | (b) (4) Taylor Wilson (b) (4) | 15 Feb 2021 18:53:17 |

US3722338

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:26:23

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 12:03:51 |
| User entered 'I' | System | 15 Feb 2021 18:53:17 |

US3722338

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:26:23

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 06:01:27 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered 'Yes (Y)' | (b) (4) Marlee Smith (b) (4) | 08 Mar 2021 21:53:07 |

US3722338

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 06:01:27 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered '8 Mar 2021' | (b) (4) Marlee Smith (b) (4) | 08 Mar 2021 21:53:07 |

US3722338

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|--------------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 06:01:27 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered 'Clinic (Clinic)' | (b) (4) Marlee Smith (b) (4) | 08 Mar 2021 21:53:07 |

US3722338

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:26:23

[Folder OID](#)

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 06:01:27 |
| User entered 'OLD57' | System | 08 Mar 2021 21:53:07 |

US3722338

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:26:23

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 06:01:27 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered 'Yes (Y)' | (b) (4) Marlee Smith (b) (4) | 08 Mar 2021 21:53:33 |

US3722338

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:26:23

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 06:01:27 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered '8 Mar 2021' | (b) (4) Marlee Smith (b) (4) | 08 Mar 2021 21:53:33 |

US3722338

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 06:01:27 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered '13:59' | (b) (4) Marlee Smith (b) (4) | 08 Mar 2021 21:53:33 |

US3722338

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 06:01:27 |
| User entered '8 Mar 2021 13:59' | System | 08 Mar 2021 21:53:33 |

US3722338

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:26:23

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 06:01:27 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered '97.8' F | (b) (4) Marlee Smith (b) (4) | 08 Mar 2021 21:53:33 |

US3722338

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:26:23

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 06:01:27 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered 'Oral (Oral)' | (b) (4) Marlee Smith (b) (4) | 08 Mar 2021 21:53:33 |

US3722338

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:26:23

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 06:01:27 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered empty. | (b) (4) Marlee Smith (b) (4) | 08 Mar 2021 21:53:33 |

US3722338

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:26:23

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 06:01:27 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered '80' | (b) (4) Marlee Smith (b) (4) | 08 Mar 2021 21:53:33 |

US3722338

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:26:23

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 06:01:27 |
| User entered 'bpm' | System | 08 Mar 2021 21:53:33 |

US3722338

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 06:01:27 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered '17' | (b) (4) Marlee Smith (b) (4) | 08 Mar 2021 21:53:33 |

US3722338

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:26:23

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 06:01:27 |
| User entered 'breaths/min' | System | 08 Mar 2021 21:53:33 |

US3722338

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:26:23

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 06:01:27 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered '120' | (b) (4) Marlee Smith (b) (4) | 08 Mar 2021 21:53:33 |

US3722338

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:26:23

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 06:01:27 |
| User entered 'mmHg' | System | 08 Mar 2021 21:53:33 |

US3722338

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:26:23

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 06:01:27 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered '66' | (b) (4) Marlee Smith (b) (4) | 08 Mar 2021 21:53:33 |

US3722338

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:26:23

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 06:01:27 |
| User entered 'mmHg' | System | 08 Mar 2021 21:53:33 |

US3722338

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:26:23

[Height \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 06:01:27 |

US3722338

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:26:23

Weight (derived)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 06:01:27 |

US3722338

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:26:23

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 06:01:27 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered 'No (N)' | (b) (4) Marlee Smith (b) (4) | 08 Mar 2021 21:53:42 |

US3722338

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:26:23

Date of examination (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 06:01:27 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered empty. | (b) (4) Marlee Smith (b) (4) | 08 Mar 2021 21:53:42 |

US3722338

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:26:23

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 06:01:27 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered 'Yes (Y)' | (b) (4) Marlee Smith (b) (4) | 08 Mar 2021 21:53:51 |

US3722338

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:26:23

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 06:01:27 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered '8 Mar 2021' | (b) (4) Marlee Smith (b) (4) | 08 Mar 2021 21:53:51 |

US3722338

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:26:23

Collection time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 06:01:27 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered '14:32' | (b) (4) Marlee Smith (b) (4) | 08 Mar 2021 21:53:51 |

US3722338

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:26:23

Collection date and time (derived)

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 06:01:27 |
| User entered '8 Mar 2021 14:32' | System | 08 Mar 2021 21:53:51 |

US3722338

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:26:23

[Did the participant experience any adverse events?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 10:26:35 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:27 |
| User entered 'Yes (Y)' | Amy Ford (b) (4) (b) (4) | 25 Sep 2020 15:57:32 |

US3722338

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:26:23

[AEID](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 12:00:14 |
| | | |

US3722338

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:26:23

[Adverse event](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 12:00:14 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User closed query 'Per DM CLR: To help clarify the clinical significance of the event LEFT ARM PAIN and possible association with the administration of investigational product and/or study procedure, if this event is related to the site of administration, please update the Adverse Event to "Injection site LEFT ARM PAIN"' (Site from DM). | (b) (4), (b) (6) | 19 Jan 2021 15:34:54 |
| User coded data point as SOC: General disorders and administration site conditions, HLGT: Administration site reactions, HLT: Injection site reactions, PT: Injection site pain, LLT: Injection site pain - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 13 Jan 2021 03:01:49 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 13 Jan 2021 03:01:49 |
| Query 'Per DM CLR: To help clarify the clinical significance of the event LEFT ARM PAIN and possible association with the administration of investigational product and/or study procedure, if this event is related to the site of administration, please update the Adverse Event to "Injection site LEFT ARM PAIN"' answered with 'Updated ' (Site from DM). | Sara Poff (b) (4) (b) (4) | 13 Jan 2021 03:00:38 |
| Data point term sent to Coder | System | 13 Jan 2021 03:00:32 |
| Coding entries removed. | Sara Poff (b) (4) (b) (4) | 13 Jan 2021 03:00:29 |
| User entered 'LEFT ARM injection site PAIN' reason for change: Data Entry Error | Sara Poff (b) (4) (b) (4) | 13 Jan 2021 03:00:29 |

US3722338

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:26:23

[Adverse event](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User opened query 'Per DM CLR: To help clarify the clinical significance of the event LEFT ARM PAIN and possible association with the administration of investigational product and/or study procedure, if this event is related to the site of administration, please update the Adverse Event to "Injection site LEFT ARM PAIN"' (Site from DM). | (b) (4), (b) (6) | 30 Nov 2020 14:34:45 |
| Query 'Per DM CLR: Was this a Solicited Adverse Reaction? = YES. However, Arm Pain is not a solicited event for this study. Please review and update response to 'Was this a Solicited Adverse Reaction?' as appropriate. Otherwise, update to record the actual solicited event term.' canceled (Site from DM). | (b) (4), (b) (6) | 23 Oct 2020 23:11:34 |
| User opened query 'Per DM CLR: Was this a Solicited Adverse Reaction? = YES. However, Arm Pain is not a solicited event for this study. Please review and update response to 'Was this a Solicited Adverse Reaction?' as appropriate. Otherwise, update to record the actual solicited event term.' (Site from DM). | (b) (4), (b) (6) | 20 Oct 2020 19:33:55 |
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Pain in extremity, LLT: Painful L arm - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 25 Sep 2020 16:53:42 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 25 Sep 2020 16:53:42 |
| Data point term sent to Coder | System | 25 Sep 2020 15:59:14 |
| User entered 'Left arm pain' | Amy Ford (b) (4) (b) (4) | 25 Sep 2020 15:58:56 |

US3722338

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:26:23

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 12:00:14 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered 'No (N)' | Amy Ford (b) (4) (b) (4) | 25 Sep 2020 15:58:56 |

US3722338

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:26:23

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---|------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 12:00:14 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User closed query 'Per DM CLR: Was this a Solicited Adverse Reaction? = YES. However, Arm Pain is not a solicited event for this study. Please review and update response to 'Was this a Solicited Adverse Reaction?' as appropriate. Otherwise, update to record the actual solicited event term. ' (Site from DM). | (b) (4), (b) (6) | 09 Nov 2020 16:28:40 |
| Query 'Per DM CLR: Was this a Solicited Adverse Reaction? = YES. However, Arm Pain is not a solicited event for this study. Please review and update response to 'Was this a Solicited Adverse Reaction?' as appropriate. Otherwise, update to record the actual solicited event term. ' answered with 'This was injection site pain. ' (Site from DM). | Sara Poff (b) (4) (b) (4) | 03 Nov 2020 18:59:21 |
| User entered 'No (N)' reason for change: Data Entry Error | Sara Poff (b) (4) (b) (4) | 03 Nov 2020 18:58:52 |
| User opened query 'Per DM CLR: Was this a Solicited Adverse Reaction? = YES. However, Arm Pain is not a solicited event for this study. Please review and update response to 'Was this a Solicited Adverse Reaction?' as appropriate. Otherwise, update to record the actual solicited event term. ' (Site from DM). | (b) (4), (b) (6) | 23 Oct 2020 23:11:40 |
| User entered 'Yes (Y)' | Amy Ford (b) (4) (b) (4) | 25 Sep 2020 15:58:56 |

US3722338

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:26:23

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 12:00:14 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered 'No (N)' | Amy Ford (b) (4) | 25 Sep 2020 15:58:56 |
| | (b) (4) | |

US3722338

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:26:23

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 12:00:14 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered '19 Sep 2020' | Amy Ford (b) (4) (b) (4) | 25 Sep 2020 15:58:56 |

US3722338

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:26:23

Start time (00:00-23:59)

| Audit | User | Time (GMT) |
|------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 12:00:14 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered empty. | Amy Ford (b) (4) (b) (4) | 25 Sep 2020 15:58:56 |

US3722338

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:26:23

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 12:00:14 |
| User entered empty. | System | 25 Sep 2020 15:58:56 |

US3722338

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:26:23

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---|------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 12:00:14 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| 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 or if it occurs intermittently, please update the AE term to include "INTERMITTENT". ' (Site from DM). | (b) (4), (b) (6) | 13 Jan 2021 16:53:41 |
| 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 or if it occurs intermittently, please update the AE term to include "INTERMITTENT". ' answered with 'Updated per subject ' (Site from DM). | Sara Poff (b) (4) (b) (4) | 13 Jan 2021 03:00:52 |
| User entered 'No (N)' reason for change: Data Entry Error | Sara Poff (b) (4) (b) (4) | 13 Jan 2021 03:00:29 |
| 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 or if it occurs intermittently, please update the AE term to include "INTERMITTENT". ' (Site from DM). | (b) (4), (b) (6) | 30 Nov 2020 02:02:26 |
| User entered 'Yes (Y)' | Amy Ford (b) (4) (b) (4) | 25 Sep 2020 15:58:56 |

US3722338

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:26:23

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|-------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 12:00:14 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered '23 Sep 2020' reason for change: Data Entry Error | Sara Poff (b) (4) | 13 Jan 2021 03:00:29 |
| User entered empty. | Amy Ford (b) (4) | 25 Sep 2020 15:58:56 |

US3722338

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:26:23

End time (00:00-23:59)

| Audit | User | Time (GMT) |
|------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 12:00:14 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered empty. | Amy Ford (b) (4) (b) (4) | 25 Sep 2020 15:58:56 |

US3722338

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:26:23

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 12:00:14 |
| User entered empty. | System | 25 Sep 2020 15:58:56 |

US3722338

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:26:23

[Severity](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 12:00:14 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' | Amy Ford (b) (4) (b) (4) | 25 Sep 2020 15:58:56 |

US3722338

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:26:23

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 12:00:14 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered 'No (N)' | Amy Ford (b) (4) (b) (4) | 25 Sep 2020 15:58:56 |

US3722338

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:26:23

Death

| Audit | User | Time (GMT) |
|------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 12:00:14 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered '0' | Amy Ford (b) (4) (b) (4) | 25 Sep 2020 15:58:56 |

US3722338

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:26:23

[Life threatening](#)

| Audit | User | Time (GMT) |
|------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 12:00:14 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered '0' | Amy Ford (b) (4) (b) (4) | 25 Sep 2020 15:58:56 |

US3722338

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:26:23

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 12:00:14 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered '0' | Amy Ford (b) (4) (b) (4) | 25 Sep 2020 15:58:56 |

US3722338

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:26:23

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 12:00:14 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered empty. | Amy Ford (b) (4) (b) (4) | 25 Sep 2020 15:58:56 |

US3722338

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:26:23

Hospital Discharge Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 12:00:14 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered empty. | Amy Ford (b) (4) (b) (4) | 25 Sep 2020 15:58:56 |

US3722338

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:26:23

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 12:00:14 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered empty. | Amy Ford (b) (4) (b) (4) | 25 Sep 2020 15:58:56 |

US3722338

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:26:23

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 12:00:14 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered empty. | Amy Ford (b) (4) (b) (4) | 25 Sep 2020 15:58:56 |

US3722338

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:26:23

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 12:00:14 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered '0' | Amy Ford (b) (4) (b) (4) | 25 Sep 2020 15:58:56 |

US3722338

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:26:23

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 12:00:14 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered '0' | Amy Ford (b) (4) (b) (4) | 25 Sep 2020 15:58:56 |

US3722338

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:26:23

[Other medically important event](#)

| Audit | User | Time (GMT) |
|------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 12:00:14 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered '0' | Amy Ford (b) (4) (b) (4) | 25 Sep 2020 15:58:56 |

US3722338

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:26:23

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 12:00:14 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered 'Related (RELATED)' | Amy Ford (b) (4) (b) (4) | 25 Sep 2020 15:58:56 |

US3722338

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:26:23

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 12:00:14 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered 'Not Related (NOT RELATED)' | Amy Ford (b) (4) (b) (4) | 25 Sep 2020 15:58:56 |

US3722338

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:26:23

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 12:00:14 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered 'None (NONE)' | Amy Ford (b) (4) (b) (4) | 25 Sep 2020 15:58:56 |

US3722338

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:26:23

None

| Audit | User | Time (GMT) |
|------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 12:00:14 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered '0' | Amy Ford (b) (4) (b) (4) | 25 Sep 2020 15:58:56 |

US3722338

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:26:23

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 12:00:14 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered 'I' | Amy Ford (b) (4) | 25 Sep 2020 15:58:56 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:26:23

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 12:00:14 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered '0' | Amy Ford (b) (4) (b) (4) | 25 Sep 2020 15:58:56 |

US3722338

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:26:23

[Outcome](#)

| Audit | User | Time (GMT) |
|--|------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 12:00:14 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error | Sara Poff (b) (4) (b) (4) | 13 Jan 2021 03:00:29 |
| User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' | Amy Ford (b) (4) (b) (4) | 25 Sep 2020 15:58:56 |

US3722338

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:26:23

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit | User | Time (GMT) |
|------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 12:00:14 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered empty. | Amy Ford (b) (4) (b) (4) | 25 Sep 2020 15:58:56 |

US3722338

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:26:23

[Narrative](#)

| Audit | User | Time (GMT) |
|------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 12:00:14 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered empty. | Amy Ford (b) (4) (b) (4) | 25 Sep 2020 15:58:56 |

US3722338

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:26:23

Serious Adverse Event Derived (CSA Programming Field Only)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 12:00:14 |
| User entered '0' | System | 25 Sep 2020 15:58:56 |

US3722338

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:26:23

Medically Attended AE Derived (CSA Programming Field Only)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 12:00:14 |
| User entered '0' | System | 25 Sep 2020 15:58:56 |

US3722338

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 12:00:14 |
| | | |

US3722338

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:26:23

[AEID](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 12:00:06 |
| | | |

US3722338

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:26:23

[Adverse event](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 12:00:06 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User closed query 'Per DM CLR: To help clarify the clinical significance of the event LEFT ARM SWELLING and possible association with the administration of investigational product and/or study procedure, if this event is related to the site of administration, please update the Adverse Event to "Injection site LEFT ARM SWELLING.'" (Site from DM). | (b) (4), (b) (6) | 19 Jan 2021 15:35:02 |
| User coded data point as SOC: General disorders and administration site conditions, HLGT: Administration site reactions, HLT: Injection site reactions, PT: Injection site swelling, LLT: Injection site swelling - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 13 Jan 2021 03:02:49 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 13 Jan 2021 03:02:49 |
| Data point term sent to Coder | System | 13 Jan 2021 03:02:32 |
| Query 'Per DM CLR: To help clarify the clinical significance of the event LEFT ARM SWELLING and possible association with the administration of investigational product and/or study procedure, if this event is related to the site of administration, please update the Adverse Event to "Injection site LEFT ARM SWELLING.'" answered with 'Updated ' (Site from DM). | Sara Poff (b) (4) (b) (4) | 13 Jan 2021 03:02:28 |
| Coding entries removed. | Sara Poff (b) (4) (b) (4) | 13 Jan 2021 03:02:09 |
| User entered 'injection site LEFT ARM SWELLING' reason for change: Data Entry Error | Sara Poff (b) (4) (b) (4) | 13 Jan 2021 03:02:09 |

US3722338

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:26:23

[Adverse event](#)

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| User opened query 'Per DM CLR: To help clarify the clinical significance of the event LEFT ARM SWELLING and possible association with the administration of investigational product and/or study procedure, if this event is related to the site of administration, please update the Adverse Event to "Injection site LEFT ARM SWELLING.'" (Site from DM). | (b) (4), (b) (6) | 30 Nov 2020 14:38:41 |
| Query 'To help clarify the clinical significance of the event LEFT ARM SWELLING and possible association with the administration of investigational product and/or study procedure, if this event is related to the site of administration, please update the Adverse Event to "Injection site LEFT ARM SWELLING"' canceled (Site from DM). | (b) (4), (b) (6) | 30 Nov 2020 14:38:12 |
| User opened query 'To help clarify the clinical significance of the event LEFT ARM SWELLING and possible association with the administration of investigational product and/or study procedure, if this event is related to the site of administration, please update the Adverse Event to "Injection site LEFT ARM SWELLING"' (Site from DM). | (b) (4), (b) (6) | 30 Nov 2020 14:38:09 |
| Query 'Per DM CLR: Was this a Solicited Adverse Reaction? = YES. However, Arm Pain is not a solicited event for this study. Please review and update response to 'Was this a Solicited Adverse Reaction?' as appropriate. Otherwise, update to record the actual solicited event term.' canceled (Site from DM). | (b) (4), (b) (6) | 23 Oct 2020 23:11:54 |
| User opened query 'Per DM CLR: Was this a Solicited Adverse Reaction? = YES. However, Arm Pain is not a solicited event for this study. Please review and update response to 'Was this a Solicited Adverse Reaction?' as appropriate. Otherwise, update to record the actual solicited event term.' (Site from DM). | (b) (4), (b) (6) | 20 Oct 2020 19:34:22 |
| User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: General signs and symptoms NEC, PT: Peripheral swelling, LLT: Swelling arm - version MedDRA\23.0. | (b) (4) (b) (4) | 25 Sep 2020 18:45:50 |

US3722338

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:26:23

[Adverse event](#)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| User coded data point as Term Coded data point by | Coder Import (b) (4) | 25 Sep 2020 18:45:50 |
| User: (b) (6) - version MedDRA\23.0. | (b) (4) | |
| Data point term sent to Coder | System | 25 Sep 2020 16:00:17 |
| User entered 'Left arm swelling' | Amy Ford (b) (4) | 25 Sep 2020 16:00:05 |
| | (b) (4) | |

US3722338

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:26:23

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 12:00:06 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered 'No (N)' | Amy Ford (b) (4) (b) (4) | 25 Sep 2020 16:00:05 |

US3722338

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:26:23

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|--|------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 12:00:06 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User closed query 'Per DM CLR: Was this a Solicited Adverse Reaction? = YES. However, Arm Pain is not a solicited event for this study. Please review and update response to 'Was this a Solicited Adverse Reaction?' as appropriate. Otherwise, update to record the actual solicited event term. ' (Site from DM). | (b) (4), (b) (6) | 09 Nov 2020 16:29:00 |
| Query 'Per DM CLR: Was this a Solicited Adverse Reaction? = YES. However, Arm Pain is not a solicited event for this study. Please review and update response to 'Was this a Solicited Adverse Reaction?' as appropriate. Otherwise, update to record the actual solicited event term. ' answered with 'This was injection site swelling ' (Site from DM). | Sara Poff (b) (4) (b) (4) | 03 Nov 2020 19:01:52 |
| User entered 'No (N)' reason for change: Data Entry Error | Sara Poff (b) (4) (b) (4) | 03 Nov 2020 18:59:58 |
| User opened query 'Per DM CLR: Was this a Solicited Adverse Reaction? = YES. However, Arm Pain is not a solicited event for this study. Please review and update response to 'Was this a Solicited Adverse Reaction?' as appropriate. Otherwise, update to record the actual solicited event term. ' (Site from DM). | (b) (4), (b) (6) | 23 Oct 2020 23:12:00 |
| User entered 'Yes (Y)' | Amy Ford (b) (4) (b) (4) | 25 Sep 2020 16:00:05 |

US3722338

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:26:23

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 12:00:06 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered 'No (N)' | Amy Ford (b) (4) | 25 Sep 2020 16:00:05 |
| | (b) (4) | |

US3722338

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:26:23

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 12:00:06 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered '19 Sep 2020' | Amy Ford (b) (4) (b) (4) | 25 Sep 2020 16:00:05 |

US3722338

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:26:23

Start time (00:00-23:59)

| Audit | User | Time (GMT) |
|------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 12:00:06 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered empty. | Amy Ford (b) (4) (b) (4) | 25 Sep 2020 16:00:05 |

US3722338

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:26:23

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 12:00:06 |
| User entered empty. | System | 25 Sep 2020 16:00:05 |

US3722338

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:26:23

[Ongoing?](#)

| Audit | User | Time (GMT) |
|--|------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 12:00:06 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| 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 or if it occurs intermittently, please update the AE term to include "INTERMITTENT".' (Site from DM). | (b) (4), (b) (6) | 19 Jan 2021 13:30:06 |
| 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 or if it occurs intermittently, please update the AE term to include "INTERMITTENT".' answered with 'Updated' (Site from DM). | Sara Poff (b) (4) (b) (4) | 13 Jan 2021 03:02:36 |
| User entered 'No (N)' reason for change: Data Entry Error | Sara Poff (b) (4) (b) (4) | 13 Jan 2021 03:02:09 |
| 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 or if it occurs intermittently, please update the AE term to include "INTERMITTENT".' (Site from DM). | (b) (4), (b) (6) | 30 Nov 2020 02:02:37 |
| User entered 'Yes (Y)' | Amy Ford (b) (4) (b) (4) | 25 Sep 2020 16:00:05 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:26:23

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|-------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 12:00:06 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered '23 Sep 2020' reason for change: Data Entry Error | Sara Poff (b) (4) | 13 Jan 2021 03:02:09 |
| User entered empty. | Amy Ford (b) (4) | 25 Sep 2020 16:00:05 |

US3722338

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:26:23

End time (00:00-23:59)

| Audit | User | Time (GMT) |
|------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 12:00:06 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered empty. | Amy Ford (b) (4) (b) (4) | 25 Sep 2020 16:00:05 |

US3722338

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:26:23

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 12:00:06 |
| User entered empty. | System | 25 Sep 2020 16:00:05 |

US3722338

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:26:23

[Severity](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 12:00:06 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' | Amy Ford (b) (4) (b) (4) | 25 Sep 2020 16:00:05 |

US3722338

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:26:23

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 12:00:06 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered 'No (N)' | Amy Ford (b) (4) (b) (4) | 25 Sep 2020 16:00:05 |

US3722338

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:26:23

[Death](#)

| Audit | User | Time (GMT) |
|------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 12:00:06 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered '0' | Amy Ford (b) (4) (b) (4) | 25 Sep 2020 16:00:05 |

US3722338

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:26:23

[Life threatening](#)

| Audit | User | Time (GMT) |
|------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 12:00:06 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered '0' | Amy Ford (b) (4) (b) (4) | 25 Sep 2020 16:00:05 |

US3722338

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:26:23

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 12:00:06 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered '0' | Amy Ford (b) (4) (b) (4) | 25 Sep 2020 16:00:05 |

US3722338

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:26:23

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 12:00:06 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered empty. | Amy Ford (b) (4) (b) (4) | 25 Sep 2020 16:00:05 |

US3722338

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:26:23

Hospital Discharge Date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 12:00:06 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered empty. | Amy Ford (b) (4) (b) (4) | 25 Sep 2020 16:00:05 |

US3722338

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:26:23

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 12:00:06 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered empty. | Amy Ford (b) (4) (b) (4) | 25 Sep 2020 16:00:05 |

US3722338

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:26:23

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 12:00:06 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered empty. | Amy Ford (b) (4) (b) (4) | 25 Sep 2020 16:00:05 |

US3722338

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:26:23

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 12:00:06 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered '0' | Amy Ford (b) (4) (b) (4) | 25 Sep 2020 16:00:05 |

US3722338

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:26:23

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 12:00:06 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered '0' | Amy Ford (b) (4) (b) (4) | 25 Sep 2020 16:00:05 |

US3722338

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:26:23

[Other medically important event](#)

| Audit | User | Time (GMT) |
|------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 12:00:06 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered '0' | Amy Ford (b) (4) (b) (4) | 25 Sep 2020 16:00:05 |

US3722338

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:26:23

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 12:00:06 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered 'Related (RELATED)' | Amy Ford (b) (4) (b) (4) | 25 Sep 2020 16:00:05 |

US3722338

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:26:23

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 12:00:06 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered 'Not Related (NOT RELATED)' | Amy Ford (b) (4) (b) (4) | 25 Sep 2020 16:00:05 |

US3722338

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:26:23

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 12:00:06 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered 'None (NONE)' | Amy Ford (b) (4) (b) (4) | 25 Sep 2020 16:00:05 |

US3722338

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:26:23

None

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 12:00:06 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered '0' | Amy Ford (b) (4) | 25 Sep 2020 16:00:05 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:26:23

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 12:00:06 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered 'I' | Amy Ford (b) (4) (b) (4) | 25 Sep 2020 16:00:05 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:26:23

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 12:00:06 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered '0' | Amy Ford (b) (4) (b) (4) | 25 Sep 2020 16:00:05 |

US3722338

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:26:23

[Outcome](#)

| Audit | User | Time (GMT) |
|--|------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 12:00:06 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error | Sara Poff (b) (4) (b) (4) | 13 Jan 2021 03:02:09 |
| User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' | Amy Ford (b) (4) (b) (4) | 25 Sep 2020 16:00:05 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:26:23

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit | User | Time (GMT) |
|------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 12:00:06 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered empty. | Amy Ford (b) (4) (b) (4) | 25 Sep 2020 16:00:05 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:26:23

[Narrative](#)

| Audit | User | Time (GMT) |
|------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 12:00:06 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered empty. | Amy Ford (b) (4) (b) (4) | 25 Sep 2020 16:00:05 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:26:23

Serious Adverse Event Derived (CSA Programming Field Only)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 12:00:06 |
| User entered '0' | System | 25 Sep 2020 16:00:05 |

US3722338

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:26:23

Medically Attended AE Derived (CSA Programming Field Only)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 12:00:06 |
| User entered '0' | System | 25 Sep 2020 16:00:05 |

US3722338

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 12:00:06 |
| | | |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:26:23

[AEID](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:26:32 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Nov 2020 17:58:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:50:43 |
| User entered 'USA-US083-2020-mRNA-1273-P301000002' | System | 23 Oct 2020 19:50:37 |
| User entered 'New' | (b) (4), (b) (6) | 23 Oct 2020 19:50:37 |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:26:23

[Adverse event](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| User closed query 'PV Query: The medication tramadol and dilaudid were indicated for pain related to acute incarcerated left hernia repair with mesh. Please consider updating event term, hernia left lower quadrant to include disease progression (acute incarcerated left hernia). If not, please clarify.' (Site from Safety). | (b) (4), (b) (6) | 29 Apr 2021 02:50:05 |
| User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Hernias NEC, PT: Incarcerated hernia, LLT: Incarcerated hernia - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 28 Apr 2021 12:39:15 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 28 Apr 2021 12:39:15 |
| Data point term sent to Coder | System | 28 Apr 2021 12:31:35 |
| Query 'PV Query: The medication tramadol and dilaudid were indicated for pain related to acute incarcerated left hernia repair with mesh. Please consider updating event term, hernia left lower quadrant to include disease progression (acute incarcerated left hernia). If not, please clarify.' answered with 'updated' (Site from Safety). | Marlee Smith (b) (4) (b) (4) | 28 Apr 2021 12:31:35 |
| DataPoint Un-verified. | Marlee Smith (b) (4) (b) (4) | 28 Apr 2021 12:31:15 |
| Coding entries removed. | Marlee Smith (b) (4) (b) (4) | 28 Apr 2021 12:31:15 |
| User entered 'Acute incarcerated left HERNIA LOWER QUADRANT' reason for change: Data Entry Error | Marlee Smith (b) (4) (b) (4) | 28 Apr 2021 12:31:15 |
| User opened query 'PV Query: The medication tramadol and dilaudid were indicated for pain related to acute incarcerated left hernia repair with mesh. Please consider updating event term, hernia left lower quadrant to include disease progression (acute incarcerated left hernia). If not, please clarify.' (Site from Safety). | (b) (4), (b) (6) | 25 Apr 2021 17:08:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 14:18:27 |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:26:23

[Adverse event](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User coded data point as SOC: Gastrointestinal disorders, HLGT: Abdominal hernias and other abdominal wall conditions, HLT: Abdominal hernias NEC, PT: Abdominal hernia, LLT: Abdominal hernia - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 08 Apr 2021 10:46:44 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 08 Apr 2021 10:46:44 |
| Data point term sent to Coder | System | 07 Apr 2021 17:09:56 |
| User closed query 'For coding purposes, please specify the location of the HERNIA and update the term with your response' (Site from System). | System | 07 Apr 2021 17:09:17 |
| Query 'For coding purposes, please specify the location of the HERNIA and update the term with your response' answered with 'updated' (Site from System). | Marlee Smith (b) (4) (b) (4) | 07 Apr 2021 17:09:17 |
| Coding entries removed. | Marlee Smith (b) (4) (b) (4) | 07 Apr 2021 17:09:10 |
| User entered 'HERNIA left lower quadrant' reason for change: Data Entry Error | Marlee Smith (b) (4) (b) (4) | 07 Apr 2021 17:09:10 |
| User opened query 'For coding purposes, please specify the location of the HERNIA and update the term with your response' (Site from System). | Coder Import (b) (4) (b) (4) | 30 Mar 2021 17:48:01 |
| User closed query 'Per DM CLR: Surgery/procedures are not to be recorded as Adverse Events. Please record the underlying medical condition/diagnosis and update the AE as appropriate. Please ensure the surgery/procedure is recorded on the Con Proc eCRF.' (Site from DM). | (b) (4), (b) (6) (b) (4) | 09 Mar 2021 13:12:29 |
| User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Hernias NEC, PT: Hernia, LLT: Hernia - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 09 Mar 2021 02:44:07 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 09 Mar 2021 02:44:07 |
| Data point term sent to Coder | System | 09 Mar 2021 02:42:36 |
| Query 'Per DM CLR: Surgery/procedures are not to be recorded as Adverse Events. Please record the underlying medical condition/diagnosis and update the AE as appropriate. Please ensure the surgery/procedure is recorded on the Con Proc eCRF.' answered with 'Updated name' (Site from DM). | Kayla Peay (b) (4) (b) (4) | 09 Mar 2021 02:41:58 |

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:26:23

[Adverse event](#)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| DataPoint Un-verified. | Kayla Peay (b) (4) | 09 Mar 2021 02:41:48 |
| | (b) (4) | |
| Coding entries removed. | Kayla Peay (b) (4) | 09 Mar 2021 02:41:48 |
| | (b) (4) | |
| User entered 'Hernia' reason for change: Data Entry Error | Kayla Peay (b) (4) | 09 Mar 2021 02:41:48 |
| | (b) (4) | |
| User opened query 'Per DM CLR: Surgery/procedures are not to be recorded as Adverse Events. Please record the underlying medical condition/diagnosis and update the AE as appropriate. Please ensure the surgery/procedure is recorded on the Con Proc eCRF.' (Site from DM). | (b) (4), (b) (6) | 23 Feb 2021 07:52:47 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:26:34 |
| | (b) (4), (b) (6) | |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| | (b) (4), (b) (6) | |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| | (b) (4), (b) (6) | |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| | (b) (4), (b) (6) | |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| | (b) (4), (b) (6) | |
| User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Hernias NEC, PT: Incarcerated hernia, LLT: Incarcerated hernia - version MedDRA\\23.0. | Coder Import (b) (4) | 19 Jan 2021 12:21:05 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) | 19 Jan 2021 12:21:05 |
| | (b) (4) | |
| Data point term sent to Coder | System | 19 Jan 2021 09:52:59 |
| Coding entries removed. | Kayla Peay (b) (4) | 19 Jan 2021 09:52:01 |
| | (b) (4) | |
| User entered 'Acute Incarcerated Left Hernia Repair with Mesh' reason for change: Data Entry Error | Kayla Peay (b) (4) | 19 Jan 2021 09:52:01 |
| | (b) (4) | |
| User closed query 'PV Query: reported event term is a procedure. Please consider updating event term to diagnosis: Umbilical hernia.' (Site from Safety). | (b) (4), (b) (6) | 25 Nov 2020 19:11:22 |
| | (b) (4), (b) (6) | |
| User coded data point as SOC: Gastrointestinal disorders, HLGT: Abdominal hernias and other abdominal wall conditions, HLT: Umbilical hernias, PT: Umbilical hernia, LLT: Umbilical hernia - version MedDRA\\23.0. | Coder Import (b) (4) | 24 Nov 2020 22:26:01 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:26:23

[Adverse event](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User coded data point as Term Coded data point by | Coder Import (b) (4) | 24 Nov 2020 22:26:01 |
| User: Coder System - version MedDRA\\23.0. | (b) (4) | |
| Data point term sent to Coder | System | 24 Nov 2020 22:25:44 |
| Query 'PV Query: reported event term is a procedure. | Sara Poff (b) (4) | 24 Nov 2020 22:25:20 |
| Please consider updating event term to diagnosis: | (b) (4) | |
| Umbilical hernia.' answered with 'Updated' (Site from | | |
| Safety). | | |
| DataPoint Un-verified. | Sara Poff (b) (4) | 24 Nov 2020 22:25:08 |
| | (b) (4) | |
| Coding entries removed. | Sara Poff (b) (4) | 24 Nov 2020 22:25:08 |
| | (b) (4) | |
| User entered 'UMBILICAL HERNIA' reason for | Sara Poff (b) (4) | 24 Nov 2020 22:25:08 |
| change: Data Entry Error | (b) (4) | |
| User opened query 'PV Query: reported event term is | (b) (4), (b) (6) | 13 Nov 2020 18:39:09 |
| a procedure. Please consider updating event term to | | |
| diagnosis: Umbilical hernia.' (Site from Safety). | | |
| Query 'Safety Medical Query: reported event term is | (b) (4), (b) (6) | 13 Nov 2020 18:39:05 |
| a procedure. Please consider updating event term to | | |
| diagnosis: Umbilical hernia.' canceled (Site from | | |
| Safety). | | |
| User opened query 'Safety Medical Query: reported | (b) (4), (b) (6) | 13 Nov 2020 18:38:54 |
| event term is a procedure. Please consider updating | | |
| event term to diagnosis: Umbilical hernia.' (Site from | | |
| Safety). | | |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Nov 2020 01:50:28 |
| | | |
| User closed query 'PV Query: The reported event | (b) (4), (b) (6) | 05 Nov 2020 14:07:06 |
| term of hernia repair is a surgical procedure. Please | | |
| consider to update the event term with the diagnosis | | |
| (i.e. umbilical, femoral, inguinal hernia, etc)' (Site | | |
| from Safety). | | |
| Query 'PV Query: The reported event term of hernia | Sara Poff (b) (4) | 04 Nov 2020 21:15:54 |
| repair is a surgical procedure. Please consider to | (b) (4) | |
| update the event term with the diagnosis (i.e. | | |
| umbilical, femoral, inguinal hernia, etc)' answered | | |
| with 'Completed ' (Site from Safety). | | |
| User coded data point as SOC: Surgical and medical | Coder Import (b) (4) | 03 Nov 2020 19:05:25 |
| procedures, HLGT: Gastrointestinal therapeutic | (b) (4) | |
| procedures, HLT: Hernia repairs, PT: Umbilical | | |
| hernia repair, LLT: Umbilical hernia repair - version | | |
| MedDRA\\23.0. | | |

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Generated On: 10 Jun 2021 09:26:23

[Adverse event](#)

| Audit | User | Time (GMT) |
|---|---|--|
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. Data point term sent to Coder Coding entries removed. | Coder Import (b) (4) (b) (4) System Sara Poff (b) (4) (b) (4) | 03 Nov 2020 19:05:25 03 Nov 2020 19:04:21 03 Nov 2020 19:04:20 |
| User entered 'Umbilical HERNIA REPAIR' reason for change: Data Entry Error | Sara Poff (b) (4) (b) (4) | 03 Nov 2020 19:04:20 |
| User opened query 'PV Query: The reported event term of hernia repair is a surgical procedure. Please consider to update the event term with the diagnosis (i.e. umbilical, femoral, inguinal hernia, etc)' (Site from Safety). | (b) (4), (b) (6) | 29 Oct 2020 18:33:08 |
| User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Hernia repairs, PT: Hernia repair, LLT: Hernia repair - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 22 Oct 2020 19:47:46 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. Data point term sent to Coder | Coder Import (b) (4) (b) (4) System | 22 Oct 2020 19:47:46 22 Oct 2020 19:46:45 |
| User entered 'Hernia repair' | Amy Ford (b) (4) (b) (4) | 22 Oct 2020 19:46:15 |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:26:23

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:26:35 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Nov 2020 17:58:38 |
| User entered 'Yes (Y)' | Amy Ford (b) (4) (b) (4) | 22 Oct 2020 19:46:15 |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:26:23

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:26:37 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Nov 2020 17:58:41 |
| User entered 'No (N)' | Amy Ford (b) (4) (b) (4) | 22 Oct 2020 19:46:15 |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:26:23

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:26:38 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Nov 2020 17:58:48 |
| User entered 'No (N)' | Amy Ford (b) (4) (b) (4) | 22 Oct 2020 19:46:15 |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:26:23

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:26:40 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered '12 Oct 2020' reason for change: Data Entry Error | Kayla Peay (b) (4) | 19 Jan 2021 09:52:01 |
| User entered '13 Oct 2020' | Amy Ford (b) (4) | 22 Oct 2020 19:46:15 |

US3722338

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:26:23

Start time (00:00-23:59)

| Audit | User | Time (GMT) |
|------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:26:41 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Nov 2020 17:58:51 |
| User entered empty. | Amy Ford (b) (4) (b) (4) | 22 Oct 2020 19:46:15 |

US3722338

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:26:23

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 22 Oct 2020 19:46:15 |

US3722338

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:26:23

[Ongoing?](#)

| Audit | User | Time (GMT) |
|------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:26:43 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Nov 2020 17:59:15 |
| User entered 'No (N)' | Amy Ford (b) (4) (b) (4) | 22 Oct 2020 19:46:15 |

US3722338

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:26:23

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:26:44 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered '21 Oct 2020' | Amy Ford (b) (4) (b) (4) | 22 Oct 2020 19:46:15 |

US3722338

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:26:23

End time (00:00-23:59)

| Audit | User | Time (GMT) |
|------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:26:54 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Nov 2020 17:59:16 |
| User entered empty. | Amy Ford (b) (4) (b) (4) | 22 Oct 2020 19:46:15 |

US3722338

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:26:23

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 22 Oct 2020 19:46:15 |

US3722338

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:26:23

[Severity](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:26:56 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Nov 2020 17:59:23 |
| User entered 'Grade 3/Severe (Grade 3/Severe)' | Amy Ford (b) (4) (b) (4) | 22 Oct 2020 19:46:15 |

US3722338

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:26:23

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:26:57 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Nov 2020 17:59:32 |
| User entered 'Yes (Y)' | Amy Ford (b) (4) (b) (4) | 22 Oct 2020 19:46:15 |

US3722338

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:26:23

[Death](#)

| Audit | User | Time (GMT) |
|------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:26:59 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Nov 2020 17:59:35 |
| User entered '0' | Amy Ford (b) (4) (b) (4) | 22 Oct 2020 19:46:15 |

US3722338

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:26:23

[Life threatening](#)

| Audit | User | Time (GMT) |
|------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:27:01 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Nov 2020 17:59:36 |
| User entered '0' | Amy Ford (b) (4) (b) (4) | 22 Oct 2020 19:46:15 |

US3722338

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:26:23

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:27:03 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Nov 2020 01:50:39 |
| User entered 'I' | Amy Ford (b) (4) (b) (4) | 22 Oct 2020 19:46:15 |

US3722338

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:26:23

Hospital Admission Date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:27:07 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| DataPoint Un-verified. | Kayla Peay (b) (4) | 19 Jan 2021 09:52:01 |
| User entered '12 Oct 2020' reason for change: Data Entry Error | (b) (4) | |
| | Kayla Peay (b) (4) | 19 Jan 2021 09:52:01 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 11 Nov 2020 01:51:28 |
| User entered '13 Oct 2020' | Amy Ford (b) (4) | 22 Oct 2020 19:46:15 |
| | (b) (4) | |

US3722338

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:26:23

Hospital Discharge Date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:27:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| User closed query 'PV Query: Subject was hospitalized for 9 days Was there a clinical issue for the prolonged hospitalization or was this simply normal recovery time?' (Site from Safety). | (b) (4), (b) (6) | 25 Nov 2020 19:11:39 |
| Query 'PV Query: Subject was hospitalized for 9 days Was there a clinical issue for the prolonged hospitalization or was this simply normal recovery time?' answered with 'Subject is lost to follow up. A certified letter has been sent with a medical release form ' (Site from Safety). | Sara Poff (b) (4) (b) (4) | 24 Nov 2020 22:05:41 |
| User opened query 'PV Query: Subject was hospitalized for 9 days Was there a clinical issue for the prolonged hospitalization or was this simply normal recovery time?' (Site from Safety). | (b) (4), (b) (6) | 13 Nov 2020 18:39:26 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Nov 2020 01:51:38 |
| User entered '21 Oct 2020' | Amy Ford (b) (4) (b) (4) | 22 Oct 2020 19:46:15 |

US3722338

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:26:23

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 14:17:38 |
| User closed query 'Per medical records, it appears subject was transferred to the ICU post-op. ' (Site from CRA). | (b) (4), (b) (6) | 22 Mar 2021 16:29:24 |
| User entered 'No (N)' reason for change: Data Entry Error | Kayla Peay (b) (4) | 09 Mar 2021 02:41:48 |
| Query 'Per medical records, it appears subject was transferred to the ICU post-op. ' answered with 'updated' (Site from CRA). | Marlee Smith (b) (4) | 18 Feb 2021 15:43:36 |
| DataPoint Un-verified. | Marlee Smith (b) (4) | 18 Feb 2021 15:43:29 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Marlee Smith (b) (4) | 18 Feb 2021 15:43:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| User opened query 'Per medical records, it appears subject was transferred to the ICU post-op. ' (Site from CRA). | (b) (4), (b) (6) | 03 Feb 2021 19:27:37 |
| Query 'Please update your answer since subject has returned to study site and medical records have been obtained.' canceled (Site from CRA). | (b) (4), (b) (6) | 03 Feb 2021 19:27:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:11 |
| User opened query 'Please update your answer since subject has returned to study site and medical records have been obtained.' (Site from CRA). | (b) (4), (b) (6) | 20 Jan 2021 15:32:11 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 20 Jan 2021 15:30:41 |
| User closed query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System). | (b) (4), (b) (6) | 11 Nov 2020 06:30:57 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Nov 2020 01:51:53 |

US3722338

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:26:23

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---|-------------------|----------------------|
| Query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered with 'Subject is lost to follow up therefore unable to confirm.' (Site from System). | Sara Poff (b) (4) | 10 Nov 2020 21:52:33 |
| User opened query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System). | System | 22 Oct 2020 19:46:15 |
| User entered 'Unknown (UNK)' | Amy Ford (b) (4) | 22 Oct 2020 19:46:15 |

US3722338

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:26:23

Number of Days in ICU

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| User closed query 'Admitted to ICU? is Yes, however Number of Days in ICU is missing. Please review and reconcile.' (Site from System). | (b) (4), (b) (6) | 10 Mar 2021 11:01:54 |
| Query 'Admitted to ICU? is Yes, however Number of Days in ICU is missing. Please review and reconcile.' answered with 'error' (Site from System). | Kayla Peay (b) (4) | 09 Mar 2021 02:41:26 |
| User opened query 'Admitted to ICU? is Yes, however Number of Days in ICU is missing. Please review and reconcile.' (Site from System). | System | 18 Feb 2021 15:43:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:27:43 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Nov 2020 01:51:59 |
| User entered empty. | Amy Ford (b) (4) | 22 Oct 2020 19:46:15 |

US3722338

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:26:23

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:27:45 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Nov 2020 01:52:06 |
| User entered '0' | Amy Ford (b) (4) (b) (4) | 22 Oct 2020 19:46:15 |

US3722338

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:26:23

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:27:48 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Nov 2020 01:52:11 |
| User entered '0' | Amy Ford (b) (4) (b) (4) | 22 Oct 2020 19:46:15 |

US3722338

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:26:23

[Other medically important event](#)

| Audit | User | Time (GMT) |
|------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:27:49 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Nov 2020 01:52:16 |
| User entered '0' | Amy Ford (b) (4) (b) (4) | 22 Oct 2020 19:46:15 |

US3722338

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:26:23

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:27:51 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Nov 2020 01:52:39 |
| User entered 'Not Related (NOT RELATED)' | Amy Ford (b) (4) (b) (4) | 22 Oct 2020 19:46:15 |

US3722338

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:26:23

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:27:52 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Nov 2020 01:52:43 |
| User entered 'Not Related (NOT RELATED)' | Amy Ford (b) (4) (b) (4) | 22 Oct 2020 19:46:15 |

US3722338

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:26:23

Action taken with investigational product

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:27:54 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Nov 2020 01:52:54 |
| User closed query 'PV Query: As the last dose of study drug was given on 17 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety). | (b) (4), (b) (6) | 04 Nov 2020 15:01:09 |
| Query 'PV Query: As the last dose of study drug was given on 17 Sep 2020, please update the action taken with study drug from none to not applicable.' answered with 'updated' (Site from Safety). | Amy Ford (b) (4) | 03 Nov 2020 15:05:31 |
| User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error | (b) (4) | 03 Nov 2020 15:05:19 |
| User opened query 'PV Query: As the last dose of study drug was given on 17 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety). | (b) (4), (b) (6) | 29 Oct 2020 18:32:54 |
| User entered 'None (NONE)' | Amy Ford (b) (4) | 22 Oct 2020 19:46:15 |
| | (b) (4) | |

US3722338

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:26:23

None

| Audit | User | Time (GMT) |
|--|------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:27:58 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User closed query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Procedure (#1) recorded that matches this AE during this timeframe. Please review and update this field. ' (Site from DM). | (b) (4), (b) (6) | 13 Jan 2021 16:46:46 |
| Query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Procedure (#1) recorded that matches this AE during this timeframe. Please review and update this field. ' answered with 'Updated ' (Site from DM). | Sara Poff (b) (4) (b) (4) | 13 Jan 2021 03:03:42 |
| DataPoint Un-verified. | Sara Poff (b) (4) (b) (4) | 13 Jan 2021 03:03:28 |
| User entered '0' reason for change: Data Entry Error | Sara Poff (b) (4) (b) (4) | 13 Jan 2021 03:03:28 |
| User opened query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Procedure (#1) recorded that matches this AE during this timeframe. Please review and update this field. ' (Site from DM). | (b) (4), (b) (6) | 12 Dec 2020 12:06:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Nov 2020 01:53:04 |
| User entered '1' | Amy Ford (b) (4) (b) (4) | 22 Oct 2020 19:46:15 |

US3722338

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:26:23

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|--|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:28:00 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| DataPoint Un-verified. | Sara Poff (b) (4) | 13 Jan 2021 03:03:28 |
| User entered '1' reason for change: Data Entry Error | (b) (4) | |
| | Sara Poff (b) (4) | 13 Jan 2021 03:03:28 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 11 Nov 2020 01:53:08 |
| User entered '0' | Amy Ford (b) (4) | 22 Oct 2020 19:46:15 |
| | (b) (4) | |

US3722338

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:26:23

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|--|-------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:28:01 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| DataPoint Un-verified. | Sara Poff (b) (4) | 13 Jan 2021 03:03:28 |
| User entered '1' reason for change: Data Entry Error | (b) (4) | |
| | Sara Poff (b) (4) | 13 Jan 2021 03:03:28 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 11 Nov 2020 01:53:12 |
| User entered '0' | | |
| | Amy Ford (b) (4) | 22 Oct 2020 19:46:15 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:26:23

[Outcome](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:28:03 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Nov 2020 02:04:35 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | Amy Ford (b) (4) (b) (4) | 22 Oct 2020 19:46:15 |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:26:23

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit | User | Time (GMT) |
|------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:28:05 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Nov 2020 02:04:40 |
| User entered empty. | Amy Ford (b) (4) (b) (4) | 22 Oct 2020 19:46:15 |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:26:23

[Narrative](#)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| User closed query 'Per DM CLR: Narrative = SUBJECT HAD LONGSTANDING HERNIA. However, please review and verify if this should be recorded as part of the subject's Medical History. If yes, ensure to record this medical condition in the MH eCRF as appropriate.' (Site from DM). DataPoint Verified. | (b) (4), (b) (6) | 12 Apr 2021 12:52:45 |
| Query 'Per DM CLR: Narrative = SUBJECT HAD LONGSTANDING HERNIA. However, please review and verify if this should be recorded as part of the subject's Medical History. If yes, ensure to record this medical condition in the MH eCRF as appropriate.' answered with 'updated' (Site from DM). | Marlee Smith (b) (4) | 07 Apr 2021 17:15:52 |
| User closed query 'Per DM CLR: Narrative = WAS ADMITTED TO THE HOSPITAL AROUND 13OCT2020. However, this does not correspond to the recorded Admission date above. Please review and reconcile data as appropriate.' (Site from DM). | (b) (4), (b) (6) | 06 Apr 2021 17:20:13 |
| Query 'Per DM CLR: Narrative = WAS ADMITTED TO THE HOSPITAL AROUND 13OCT2020. However, this does not correspond to the recorded Admission date above. Please review and reconcile data as appropriate.' answered with 'updated' (Site from DM). | Marlee Smith (b) (4) | 01 Apr 2021 15:13:33 |
| DataPoint Un-verified. | Marlee Smith (b) (4) | 01 Apr 2021 15:13:27 |
| User entered 'SUBJECT CONTACTED SITE AND STATED THAT HE WAS ADMITTED TO THE HOSPITAL AROUND 12OCT2020 FOR HERNIA REPAIR. SITE TO REPORT SAE TODAY AND WILL OBTAIN MEDICAL RECORD RELEASE TO OBTAIN MEDICAL RECORDS. AFTER MANY UNSUCCESSFUL ATTEMPTS BY SITE TO GET SUBJECT IN FOR MEDICAL RECORDS RELEASE, THE SUBJECT CAME IN FOR THE UNBLINDING VISIT AND A RELEASE WAS OBTAINED. MEDICAL RECORDS WERE RECEIVED FOR FOLLOW UP. SUBJECT HAD LONGSTANDING HERNIA THAT WAS REPAIRED WITH MESH ON 12 OCT 2020.' | Marlee Smith (b) (4) | 01 Apr 2021 15:13:27 |
| reason for change: Data Entry Error | | |

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:26:23

[Narrative](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| User opened query 'Per DM CLR: Narrative = SUBJECT HAD LONGSTANDING HERNIA. However, please review and verify if this should be recorded as part of the subject's Medical History. If yes, ensure to record this medical condition in the MH eCRF as appropriate.' (Site from DM). | (b) (4), (b) (6) | 27 Mar 2021 02:18:20 |
| User opened query 'Per DM CLR: Narrative = WAS ADMITTED TO THE HOSPITAL AROUND 13OCT2020. However, this does not correspond to the recorded Admission date above. Please review and reconcile data as appropriate.' (Site from DM). | (b) (4), (b) (6) | 27 Mar 2021 02:18:15 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:28:08 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered 'SUBJECT CONTACTED SITE AND STATED THAT HE WAS ADMITTED TO THE HOSPITAL AROUND 13OCT2020 FOR HERNIA REPAIR. SITE TO REPORT SAE TODAY AND WILL OBTAIN MEDICAL RECORD RELEASE TO OBTAIN MEDICAL RECORDS. | Kayla Peay (b) (4) | 19 Jan 2021 09:52:01 |
| After many unsuccessful attempts by site to get subject in for Medical Records Release, the subject came in for the unblinding visit and a release was obtained. Medical records were received for follow up. Subject had longstanding hernia that was repaired with mesh on 12 OCT 2020.' reason for change: Data Entry Error | | |
| User closed query 'PV Query: After certified letter was sent and all measures have been exhausted to obtain further information, please confirm no additional information is available. If further information is received please provide (when available). ' (Site from Safety). | (b) (4), (b) (6) | 13 Jan 2021 17:04:16 |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:26:23

[Narrative](#)

| Audit | User | Time (GMT) |
|---|------------------------------|----------------------|
| User closed query 'PV Query: Subject was hospitalized for 9 days. Was there a clinical issue for the prolonged hospitalization or was this simply normal recovery time? ' (Site from Safety). | (b) (4), (b) (6) | 13 Jan 2021 17:03:20 |
| Query 'PV Query: After certified letter was sent and all measures have been exhausted to obtain further information, please confirm no additional information is available. If further information is received please provide (when available). ' answered with 'Subject was reentered in the study per sponsor ' (Site from Safety). | Sara Poff (b) (4) (b) (4) | 13 Jan 2021 03:04:37 |
| Query 'PV Query: Subject was hospitalized for 9 days. Was there a clinical issue for the prolonged hospitalization or was this simply normal recovery time? ' answered with 'SAE has been created ' (Site from Safety). | Sara Poff (b) (4) (b) (4) | 13 Jan 2021 03:04:04 |
| User opened query 'PV Query: After certified letter was sent and all measures have been exhausted to obtain further information, please confirm no additional information is available. If further information is received please provide (when available). ' (Site from Safety). | (b) (4), (b) (6) | 04 Dec 2020 13:22:58 |
| User opened query 'PV Query: Subject was hospitalized for 9 days. Was there a clinical issue for the prolonged hospitalization or was this simply normal recovery time? ' (Site from Safety). | (b) (4), (b) (6) | 04 Dec 2020 13:22:28 |
| Query 'PV Query: Did the subject have any complications associated with hernia (i.e. incarceration, strangulation)?' canceled (Site from Safety). | (b) (4), (b) (6) | 20 Nov 2020 16:14:50 |
| Query 'PV Query: Did the subject have pre-existing hernia in medical history? If yes, please update med history eCRF accordingly.' canceled (Site from Safety). | (b) (4), (b) (6) | 20 Nov 2020 16:14:48 |
| Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' canceled (Site from Safety). | (b) (4), (b) (6) | 20 Nov 2020 16:14:47 |

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Folder: Adverse Events

Form: Adverse Events (3)

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[Narrative](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' canceled (Site from Safety). | (b) (4), (b) (6) | 20 Nov 2020 16:14:44 |
| Query 'PV Query: Please provide treatment given for the event. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' canceled (Site from Safety). | (b) (4), (b) (6) | 20 Nov 2020 16:14:43 |
| User opened query 'PV Query: Did the subject have any complications associated with hernia (i.e. incarceration, strangulation)?' (Site from Safety). | (b) (4), (b) (6) | 13 Nov 2020 18:38:35 |
| User opened query 'PV Query: Did the subject have pre-existing hernia in medical history? If yes, please update med history eCRF accordingly.' (Site from Safety). | (b) (4), (b) (6) | 13 Nov 2020 18:38:28 |
| User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety). | (b) (4), (b) (6) | 13 Nov 2020 18:37:49 |
| 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) | 13 Nov 2020 18:37:41 |
| User opened query 'PV Query: Please provide treatment given for the event. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety). | (b) (4), (b) (6) | 13 Nov 2020 18:37:34 |
| User closed query 'PV Query: Did the subject have any complications associated with hernia (i.e. incarceration, strangulation)?' (Site from Safety). | (b) (4), (b) (6) | 11 Nov 2020 14:40:36 |
| User closed query 'PV Query: Did the subject have pre-existing hernia in medical history? If yes, please update med history eCRF accordingly.' (Site from Safety). | (b) (4), (b) (6) | 11 Nov 2020 14:40:33 |

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Folder: Adverse Events

Form: Adverse Events (3)

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[Narrative](#)

| Audit | User | Time (GMT) |
|---|------------------------------|----------------------|
| User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety). | (b) (4), (b) (6) | 11 Nov 2020 14:40:30 |
| User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety). | (b) (4), (b) (6) | 11 Nov 2020 14:40:27 |
| User closed query 'PV Query: Please provide treatment given for the event. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety). | (b) (4), (b) (6) | 11 Nov 2020 14:40:24 |
| Query 'PV Query: Did the subject have any complications associated with hernia (i.e. incarceration, strangulation)?' answered with 'Subject is lost to follow up therefore unable to confirm.' (Site from Safety). | Sara Poff (b) (4) (b) (4) | 10 Nov 2020 21:54:00 |
| Query 'PV Query: Did the subject have pre-existing hernia in medical history? If yes, please update med history eCRF accordingly.' answered with 'No pre existing hernia history ' (Site from Safety). | Sara Poff (b) (4) (b) (4) | 10 Nov 2020 21:53:53 |
| Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'Subject is lost to follow up therefore unable to confirm.' (Site from Safety). | Sara Poff (b) (4) (b) (4) | 10 Nov 2020 21:52:51 |
| Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'Subject is lost to follow up therefore unable to confirm.' (Site from Safety). | Sara Poff (b) (4) (b) (4) | 10 Nov 2020 21:52:45 |
| Query 'PV Query: Please provide treatment given for the event. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'Subject is lost to follow up therefore unable to confirm.' (Site from Safety). | Sara Poff (b) (4) (b) (4) | 10 Nov 2020 21:52:40 |

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (3)

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[Narrative](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| User opened query 'PV Query: Did the subject have any complications associated with hernia (i.e. incarceration, strangulation)?' (Site from Safety). | (b) (4), (b) (6) | 29 Oct 2020 18:33:22 |
| User opened query 'PV Query: Did the subject have pre-existing hernia in medical history? If yes, please update med history eCRF accordingly.' (Site from Safety). | (b) (4), (b) (6) | 29 Oct 2020 18:33:16 |
| User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety). | (b) (4), (b) (6) | 29 Oct 2020 18:32:47 |
| 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) | 29 Oct 2020 18:32:40 |
| User opened query 'PV Query: Please provide treatment given for the event. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety). | (b) (4), (b) (6) | 29 Oct 2020 18:32:33 |
| User entered 'Subject contacted site and stated that he was admitted to the hospital around 13OCT2020 for hernia repair. Site to report SAE today and will obtain medical record release to obtain medical records.' | Amy Ford (b) (4) (b) (4) | 22 Oct 2020 19:46:15 |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:26:23

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 22 Oct 2020 19:46:15 |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:26:23

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 22 Oct 2020 19:46:15 |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '0' | System | 09 Mar 2021 02:41:48 |
| User entered '1' | System | 18 Feb 2021 15:43:29 |
| User entered '0' | System | 22 Oct 2020 19:46:15 |

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:26:23

[AEID](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:11 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:01:31 |
| User entered 'USA-US083-2021-mRNA-1273-P301000003' | System | 20 Jan 2021 17:01:27 |
| User entered 'New' | (b) (4), (b) (6) | 20 Jan 2021 17:01:27 |

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:26:23

[Adverse event](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Urinary tract infections, PT: Urinary tract infection, LLT: Urinary tract infection - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 19 Jan 2021 09:57:03 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 19 Jan 2021 09:57:03 |
| Data point term sent to Coder | System | 19 Jan 2021 09:56:00 |
| User entered 'Urinary Tract Infection' | Kayla Peay (b) (4) (b) (4) | 19 Jan 2021 09:55:08 |

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:26:23

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|------------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered 'Yes (Y)' | Kayla Peay (b) (4) (b) (4) | 19 Jan 2021 09:55:08 |

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:26:23

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|------------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered 'No (N)' | Kayla Peay (b) (4) (b) (4) | 19 Jan 2021 09:55:08 |

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:26:23

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|------------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered 'No (N)' | Kayla Peay (b) (4) (b) (4) | 19 Jan 2021 09:55:08 |

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:26:23

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered '26 Oct 2020' | Kayla Peay (b) (4) (b) (4) | 19 Jan 2021 09:55:08 |

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:26:23

Start time (00:00-23:59)

| Audit | User | Time (GMT) |
|------------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered empty. | Kayla Peay (b) (4) (b) (4) | 19 Jan 2021 09:55:08 |

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:26:23

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 19 Jan 2021 09:55:08 |

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:26:23

[Ongoing?](#)

| Audit | User | Time (GMT) |
|------------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered 'No (N)' | Kayla Peay (b) (4) (b) (4) | 19 Jan 2021 09:55:08 |

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:26:23

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 12 Apr 2021 19:15:13 |
| User closed query 'Is this the true end date, or date of hospital discharge. Please verify stop date.' (Site from CRA). | (b) (4), (b) (6) | 22 Mar 2021 16:29:37 |
| Query 'Is this the true end date, or date of hospital discharge. Please verify stop date.' answered with 'Updated to reflect resolution of condition.' (Site from CRA). | Kayla Peay (b) (4) (b) (4) | 09 Mar 2021 02:57:09 |
| DataPoint Un-verified. | Kayla Peay (b) (4) (b) (4) | 09 Mar 2021 02:56:44 |
| User entered '10 Nov 2020' reason for change: Data Entry Error | Kayla Peay (b) (4) (b) (4) | 09 Mar 2021 02:56:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| User opened query 'Is this the true end date, or date of hospital discharge. Please verify stop date.' (Site from CRA). | (b) (4), (b) (6) | 03 Feb 2021 19:45:49 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered '28 Oct 2020' | Kayla Peay (b) (4) (b) (4) | 19 Jan 2021 09:55:08 |

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:26:23

End time (00:00-23:59)

| Audit | User | Time (GMT) |
|------------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered empty. | Kayla Peay (b) (4) (b) (4) | 19 Jan 2021 09:55:08 |

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:26:23

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 19 Jan 2021 09:55:08 |

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:26:23

[Severity](#)

| Audit | User | Time (GMT) |
|--|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered 'Grade 3/Severe (Grade 3/Severe)' | Kayla Peay (b) (4) (b) (4) | 19 Jan 2021 09:55:08 |

US3722338

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:26:23

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|------------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered 'Yes (Y)' | Kayla Peay (b) (4) (b) (4) | 19 Jan 2021 09:55:08 |

US3722338

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:26:23

[Death](#)

| Audit | User | Time (GMT) |
|------------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered '0' | Kayla Peay (b) (4) (b) (4) | 19 Jan 2021 09:55:08 |

US3722338

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:26:23

[Life threatening](#)

| Audit | User | Time (GMT) |
|------------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered '0' | Kayla Peay (b) (4) (b) (4) | 19 Jan 2021 09:55:08 |

US3722338

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:26:23

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|------------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered 'I' | Kayla Peay (b) (4) (b) (4) | 19 Jan 2021 09:55:08 |

US3722338

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:26:23

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered '26 Oct 2020' | Kayla Peay (b) (4) (b) (4) | 19 Jan 2021 09:55:08 |

US3722338

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:26:23

Hospital Discharge Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered '28 Oct 2020' | Kayla Peay (b) (4) (b) (4) | 19 Jan 2021 09:55:08 |

US3722338

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:26:23

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|------------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered 'No (N)' | Kayla Peay (b) (4) (b) (4) | 19 Jan 2021 09:55:08 |

US3722338

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:26:23

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|------------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered empty. | Kayla Peay (b) (4) (b) (4) | 19 Jan 2021 09:55:08 |

US3722338

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:26:23

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|------------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered '0' | Kayla Peay (b) (4) (b) (4) | 19 Jan 2021 09:55:08 |

US3722338

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:26:23

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|------------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered '0' | Kayla Peay (b) (4) (b) (4) | 19 Jan 2021 09:55:08 |

US3722338

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:26:23

[Other medically important event](#)

| Audit | User | Time (GMT) |
|------------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered '0' | Kayla Peay (b) (4) (b) (4) | 19 Jan 2021 09:55:08 |

US3722338

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:26:23

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered 'Not Related (NOT RELATED)' | Kayla Peay (b) (4) (b) (4) | 19 Jan 2021 09:55:08 |

US3722338

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:26:23

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered 'Not Related (NOT RELATED)' | Kayla Peay (b) (4) (b) (4) | 19 Jan 2021 09:55:08 |

US3722338

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:26:23

Action taken with investigational product

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 14:51:04 |
| User closed query 'PV Query: As the last dose of study drug was given on date 17 Sep 2020, please update the action taken with study drug from none to not applicable' (Site from Safety). | (b) (4), (b) (6) | 19 Feb 2021 10:42:00 |
| Query 'PV Query: As the last dose of study drug was given on date 17 Sep 2020, please update the action taken with study drug from none to not applicable' answered with 'updated' (Site from Safety). | Marlee Smith (b) (4) | 18 Feb 2021 15:44:36 |
| DataPoint Un-verified. | (b) (4) | 18 Feb 2021 15:44:29 |
| User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error | Marlee Smith (b) (4) | 18 Feb 2021 15:44:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| User opened query 'PV Query: As the last dose of study drug was given on date 17 Sep 2020, please update the action taken with study drug from none to not applicable' (Site from Safety). | (b) (4), (b) (6) | 28 Jan 2021 20:15:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered 'None (NONE)' | Kayla Peay (b) (4) | 19 Jan 2021 09:55:08 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:26:23

None

| Audit | User | Time (GMT) |
|------------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered '0' | Kayla Peay (b) (4) (b) (4) | 19 Jan 2021 09:55:08 |

US3722338

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:26:23

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|------------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered 'I' | Kayla Peay (b) (4) (b) (4) | 19 Jan 2021 09:55:08 |

US3722338

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:26:23

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|------------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered 'I' | Kayla Peay (b) (4) (b) (4) | 19 Jan 2021 09:55:08 |

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:26:23

[Outcome](#)

| Audit | User | Time (GMT) |
|---|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | Kayla Peay (b) (4) (b) (4) | 19 Jan 2021 09:55:08 |

US3722338

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:26:23

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit | User | Time (GMT) |
|------------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered empty. | Kayla Peay (b) (4) (b) (4) | 19 Jan 2021 09:55:08 |

US3722338

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:26:23

[Narrative](#)

| Audit | User | Time (GMT) |
|--|-------------------------------|----------------------|
| User closed query 'The initial catheter placement was from 14-21OCT2020, yes the onset for the UTI attributed to improper catheter care is on 26OCT2020. Please review the dates and clarify how a catheter that was removed 5 days prior to the UTI onset caused this.' (Site from CRA). | (b) (4), (b) (6) | 22 Mar 2021 16:29:49 |
| Query 'The initial catheter placement was from 14-21OCT2020, yes the onset for the UTI attributed to improper catheter care is on 26OCT2020. Please review the dates and clarify how a catheter that was removed 5 days prior to the UTI onset caused this.' answered with 'Per records, the subject was initially discharged home with the catheter. Records state that lack of proper care for the catheter contributed to UTI. ' (Site from CRA). | Kayla Peay (b) (4) (b) (4) | 09 Mar 2021 02:56:01 |
| User opened query 'The initial catheter placement was from 14-21OCT2020, yes the onset for the UTI attributed to improper catheter care is on 26OCT2020. Please review the dates and clarify how a catheter that was removed 5 days prior to the UTI onset caused this.' (Site from CRA). | (b) (4), (b) (6) | 03 Mar 2021 18:23:51 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered 'After Foley catheter was placed for Acute Urinary Retention, subject did not provide proper care for the catheter, leading to a UTI that required hospitalization and replacement of catheter.' | Kayla Peay (b) (4) (b) (4) | 19 Jan 2021 09:55:08 |

US3722338

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:26:23

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 19 Jan 2021 09:55:08 |

US3722338

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:26:23

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 19 Jan 2021 09:55:08 |

US3722338

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '0' | System | 19 Jan 2021 09:55:08 |

US3722338

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:26:23

[AEID](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 17:36:35 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:11 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:00 |
| User entered 'USA-US083-2021-mRNA-1273-P301000003' | (b) (4), (b) (6) | 20 Jan 2021 17:01:55 |

US3722338

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:26:23

[Adverse event](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 03:21:21 |
| User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Pulmonary vascular disorders, HLT: Pulmonary thrombotic and embolic conditions, PT: Pulmonary embolism, LLT: Pulmonary embolism - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 15 Apr 2021 20:12:13 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 15 Apr 2021 20:12:13 |
| Data point term sent to Coder | System | 15 Apr 2021 20:10:46 |
| User closed query 'For coding purposes, please split HYPOXIA DUE TO RIGHT SIDED EMBOLISIM into separate entries.' (Site from System). | System | 15 Apr 2021 20:10:29 |
| Query 'For coding purposes, please split HYPOXIA DUE TO RIGHT SIDED EMBOLISIM into separate entries.' answered with 'Updated to Pulmonary Embolism with AE of hypoxia.' (Site from System). | Kayla Peay (b) (4) (b) (4) | 15 Apr 2021 20:10:29 |
| Coding entries removed. | Kayla Peay (b) (4) (b) (4) | 15 Apr 2021 20:09:55 |
| User entered 'Pulmonary Embolism' reason for change: Data Entry Error | Kayla Peay (b) (4) (b) (4) | 15 Apr 2021 20:09:55 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 14 Apr 2021 13:41:21 |
| User opened query 'For coding purposes, please split HYPOXIA DUE TO RIGHT SIDED EMBOLISIM into separate entries.' (Site from System). | Coder Import (b) (4) (b) (4) | 30 Mar 2021 18:08:00 |
| Query 'For coding purposes, please split HYPOXIA DUE TO RIGHT SIDED EMBOLISIM into separate entries. 1. HYPOXIA [DUE TO RIGHT SIDED EMBOLISIM] and 2. RIGHT SIDED EMBOLISM(SPECIFY LOCATION)' canceled (Site from Coder). | (b) (4), (b) (6) | 30 Mar 2021 14:25:41 |
| User closed query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection.' (Site from DM). | (b) (4), (b) (6) | 05 Mar 2021 06:10:41 |
| Query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection.' answered with 'subject was assessed, not COVID positive' (Site from DM). | Marlee Smith (b) (4) (b) (4) | 03 Mar 2021 18:56:18 |

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:26:23

[Adverse event](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User opened query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM). DataPoint Verified. | (b) (4), (b) (6) | 19 Feb 2021 15:47:56 |
| | (b) (4), (b) (6) | 03 Feb 2021 17:36:37 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| User coded data point as SOC: Vascular disorders, HLGT: Embolism and thrombosis, HLT: Non-site specific embolism and thrombosis, PT: Embolism, LLT: Embolism - version MedDRA\\23.0. | Coder Import (b) (4) | 22 Jan 2021 17:37:02 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) | 22 Jan 2021 17:37:02 |
| User opened query 'For coding purposes, please split HYPOXIA DUE TO RIGHT SIDED EMBOLISIM into separate entries. 1. HYPOXIA [DUE TO RIGHT SIDED EMBOLISIM] and 2. RIGHT SIDED EMBOLISM(SPECIFY LOCATION)' (Site from Coder). | (b) (4), (b) (6) | 22 Jan 2021 17:34:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| Data point term sent to Coder | System | 19 Jan 2021 09:59:01 |
| User entered 'Hypoxia due to RIght Sided Embolisim' | Kayla Peay (b) (4) | 19 Jan 2021 09:58:13 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:26:23

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|------------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 17:36:39 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered 'Yes (Y)' | Kayla Peay (b) (4) (b) (4) | 19 Jan 2021 09:58:13 |

US3722338

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:26:23

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|------------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 17:36:41 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered 'No (N)' | Kayla Peay (b) (4) (b) (4) | 19 Jan 2021 09:58:13 |

US3722338

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:26:23

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|------------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 17:36:43 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered 'No (N)' | Kayla Peay (b) (4) (b) (4) | 19 Jan 2021 09:58:13 |

US3722338

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:26:23

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:29:51 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered '26 Oct 2020' | Kayla Peay (b) (4) (b) (4) | 19 Jan 2021 09:58:13 |

US3722338

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:26:23

Start time (00:00-23:59)

| Audit | User | Time (GMT) |
|------------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:29:53 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered empty. | Kayla Peay (b) (4) (b) (4) | 19 Jan 2021 09:58:13 |

US3722338

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:26:23

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 19 Jan 2021 09:58:13 |

US3722338

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:26:23

[Ongoing?](#)

| Audit | User | Time (GMT) |
|------------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:29:57 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered 'No (N)' | Kayla Peay (b) (4) (b) (4) | 19 Jan 2021 09:58:13 |

US3722338

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:26:23

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:29:59 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered '28 Oct 2020' | Kayla Peay (b) (4) (b) (4) | 19 Jan 2021 09:58:13 |

US3722338

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:26:23

End time (00:00-23:59)

| Audit | User | Time (GMT) |
|------------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:30:01 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered empty. | Kayla Peay (b) (4) (b) (4) | 19 Jan 2021 09:58:13 |

US3722338

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:26:23

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 19 Jan 2021 09:58:13 |

US3722338

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:26:23

[Severity](#)

| Audit | User | Time (GMT) |
|--|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:30:03 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered 'Grade 3/Severe (Grade 3/Severe)' | Kayla Peay (b) (4) (b) (4) | 19 Jan 2021 09:58:13 |

US3722338

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:26:23

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|------------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:30:05 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered 'Yes (Y)' | Kayla Peay (b) (4) (b) (4) | 19 Jan 2021 09:58:13 |

US3722338

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:26:23

[Death](#)

| Audit | User | Time (GMT) |
|------------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:30:09 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered '0' | Kayla Peay (b) (4) (b) (4) | 19 Jan 2021 09:58:13 |

US3722338

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:26:23

[Life threatening](#)

| Audit | User | Time (GMT) |
|------------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:30:11 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered '0' | Kayla Peay (b) (4) (b) (4) | 19 Jan 2021 09:58:13 |

US3722338

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:26:23

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|------------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:30:14 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered 'I' | Kayla Peay (b) (4) (b) (4) | 19 Jan 2021 09:58:13 |

US3722338

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:26:23

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:30:16 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered '26 Oct 2020' | Kayla Peay (b) (4) (b) (4) | 19 Jan 2021 09:58:13 |

US3722338

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:26:23

Hospital Discharge Date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:30:18 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered '28 Oct 2020' | Kayla Peay (b) (4) (b) (4) | 19 Jan 2021 09:58:13 |

US3722338

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:26:23

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 14:52:43 |
| DataPoint Un-verified. | Marlee Smith (b) (4) | 07 Apr 2021 18:40:10 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | (b) (4) | |
| Query 'The medical record is a little confusing as at the top of the records, it lists "In Greer Memorial ICU". Please confirm this as yes or no and update as needed. or clarify otherwise.' | Marlee Smith (b) (4) | 07 Apr 2021 18:40:10 |
| canceled (Site from CRA). | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:30:23 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:30:20 |
| User opened query 'The medical record is a little confusing as at the top of the records, it lists "In Greer Memorial ICU". Please confirm this as yes or no and update as needed. or clarify otherwise.' | (b) (4), (b) (6) | 03 Feb 2021 18:28:36 |
| (Site from CRA). | | |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered 'No (N)' | Kayla Peay (b) (4) | 19 Jan 2021 09:58:13 |
| | (b) (4) | |

US3722338

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:26:23

Number of Days in ICU

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 14:52:50 |
| User closed query 'Medical records are a little unclear. at the top it notes in "greer memorial iCU" if this is confirmed, please consider updating.' (Site from CRA). | (b) (4), (b) (6) | 08 Apr 2021 14:52:48 |
| Query 'Medical records are a little unclear. at the top it notes in "greer memorial iCU" if this is confirmed, please consider updating.' answered with 'updated' (Site from CRA). | Marlee Smith (b) (4) (b) (4) | 07 Apr 2021 18:40:33 |
| DataPoint Un-verified. | Marlee Smith (b) (4) (b) (4) | 07 Apr 2021 18:40:10 |
| User entered '2' reason for change: Data Entry Error | Marlee Smith (b) (4) (b) (4) | 07 Apr 2021 18:40:10 |
| User opened query 'Medical records are a little unclear. at the top it notes in "greer memorial iCU" if this is confirmed, please consider updating.' (Site from CRA). | (b) (4), (b) (6) | 03 Feb 2021 19:30:59 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:30:25 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered empty. | Kayla Peay (b) (4) (b) (4) | 19 Jan 2021 09:58:13 |

US3722338

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:26:23

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|------------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:47:01 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 19:31:00 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:30:26 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered '0' | Kayla Peay (b) (4) (b) (4) | 19 Jan 2021 09:58:13 |

US3722338

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:26:23

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|------------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:31:02 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered '0' | Kayla Peay (b) (4) (b) (4) | 19 Jan 2021 09:58:13 |

US3722338

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:26:23

[Other medically important event](#)

| Audit | User | Time (GMT) |
|------------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered '0' | Kayla Peay (b) (4) (b) (4) | 19 Jan 2021 09:58:13 |

US3722338

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:26:23

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered 'Not Related (NOT RELATED)' | Kayla Peay (b) (4) (b) (4) | 19 Jan 2021 09:58:13 |

US3722338

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:26:23

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered 'Not Related (NOT RELATED)' | Kayla Peay (b) (4) (b) (4) | 19 Jan 2021 09:58:13 |

US3722338

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:26:23

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|--|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered 'Not Applicable (NOT APPLICABLE)' | Kayla Peay (b) (4) (b) (4) | 19 Jan 2021 09:58:13 |

US3722338

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:26:23

[None](#)

| Audit | User | Time (GMT) |
|------------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered '0' | Kayla Peay (b) (4) (b) (4) | 19 Jan 2021 09:58:13 |

US3722338

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:26:23

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM). | (b) (4), (b) (6) | 16 Mar 2021 11:49:15 |
| Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'updated' (Site from DM). | Marlee Smith (b) (4) | 09 Mar 2021 18:31:07 |
| User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM). | (b) (4), (b) (6) | 23 Feb 2021 07:53:59 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered 'I' | Kayla Peay (b) (4) | 19 Jan 2021 09:58:13 |

US3722338

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:26:23

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|------------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered '0' | Kayla Peay (b) (4) (b) (4) | 19 Jan 2021 09:58:13 |

US3722338

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:26:23

[Outcome](#)

| Audit | User | Time (GMT) |
|---|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | Kayla Peay (b) (4) (b) (4) | 19 Jan 2021 09:58:13 |

US3722338

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:26:23

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit | User | Time (GMT) |
|------------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered empty. | Kayla Peay (b) (4) (b) (4) | 19 Jan 2021 09:58:13 |

US3722338

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:26:23

[Narrative](#)

| Audit | User | Time (GMT) |
|--|-------------------------------|----------------------|
| User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. ' (Site from Safety). | (b) (4), (b) (6) | 19 Apr 2021 13:21:22 |
| User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. ' (Site from Safety). | (b) (4), (b) (6) | 19 Apr 2021 13:21:19 |
| User closed query 'PV Query: Please consider if the pulmonary embolism that led to the event hypoxia should be considered as an additional AE/SAE. ' (Site from Safety). | (b) (4), (b) (6) | 19 Apr 2021 01:28:10 |
| Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. ' answered with 'All records sent to email.' (Site from Safety). | Kayla Peay (b) (4) (b) (4) | 16 Apr 2021 13:47:13 |
| Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. ' answered with 'Records sent to email.' (Site from Safety). | Kayla Peay (b) (4) (b) (4) | 16 Apr 2021 13:45:53 |
| Query 'PV Query: Please consider if the pulmonary embolism that led to the event hypoxia should be considered as an additional AE/SAE. ' answered with 'Title of SAE changed to Pulmonary Embolism and AE of Hypoxia added. ' (Site from Safety). | Kayla Peay (b) (4) (b) (4) | 15 Apr 2021 20:09:15 |

US3722338

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:26:23

[Narrative](#)

| Audit | User | Time (GMT) |
|---|-------------------------------|----------------------|
| User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so. ' (Site from Safety). | (b) (4), (b) (6) | 10 Mar 2021 15:50:08 |
| User closed query 'PV Query: Please provide treatment given for the hypoxia including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' (Site from Safety). | (b) (4), (b) (6) | 10 Mar 2021 15:48:30 |
| Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so. ' answered with 'No COVID testing noted in records' (Site from Safety). | Kayla Peay (b) (4) (b) (4) | 09 Mar 2021 03:42:31 |
| Query 'PV Query: Please provide treatment given for the hypoxia including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' answered with 'Con Meds added' (Site from Safety). | Kayla Peay (b) (4) (b) (4) | 09 Mar 2021 03:42:17 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. ' (Site from Safety). | (b) (4), (b) (6) | 28 Jan 2021 20:17:42 |

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:26:23

[Narrative](#)

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so. ' (Site from Safety). | (b) (4), (b) (6) | 28 Jan 2021 20:17:23 |
| User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. ' (Site from Safety). | (b) (4), (b) (6) | 28 Jan 2021 20:17:09 |
| User opened query 'PV Query: Please consider if the pulmonary embolism that led to the event hypoxia should be considered as an additional AE/SAE. ' (Site from Safety). | (b) (4), (b) (6) | 28 Jan 2021 20:16:54 |
| User opened query 'PV Query: Please provide treatment given for the hypoxia including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' (Site from Safety). | (b) (4), (b) (6) | 28 Jan 2021 20:16:32 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered 'After initial hospitalization for hernia repair, subject did not take medications as prescribed, resulting in a pulmonary embolism. Subject hospitalized and discharged on 28 OCT 2020.' | Kayla Peay (b) (4) | 19 Jan 2021 09:58:13 |

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:26:23

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 19 Jan 2021 09:58:13 |

US3722338

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:26:23

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 19 Jan 2021 09:58:13 |

US3722338

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 07 Apr 2021 18:40:10 |
| User entered '0' | System | 19 Jan 2021 09:58:13 |

US3722338

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:26:23

[AEID](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Mar 2021 13:30:49 |
| Un-reviewed for Safety. | (b) (4), (b) (6) | 10 Mar 2021 13:30:45 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:20:37 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:11 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 15:44:29 |
| User entered 'USA-US083-2020-mRNA-1273-P301000002' | (b) (4), (b) (6) | 20 Jan 2021 15:44:23 |

US3722338

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:26:23

[Adverse event](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Apr 2021 19:45:01 |
| User coded data point as SOC: Renal and urinary disorders, HLGT: Urinary tract signs and symptoms, HLT: Bladder and urethral symptoms, PT: Urinary retention, LLT: Acute retention of urine - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 16 Apr 2021 14:42:54 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 16 Apr 2021 14:42:54 |
| Data point term sent to Coder | System | 16 Apr 2021 14:42:00 |
| DataPoint Un-verified. | Kayla Peay (b) (4) (b) (4) | 16 Apr 2021 14:41:40 |
| Coding entries removed. | Kayla Peay (b) (4) (b) (4) | 16 Apr 2021 14:41:40 |
| User entered 'ACUTE URINARY RETENTION' reason for change: Data Entry Error | Kayla Peay (b) (4) (b) (4) | 16 Apr 2021 14:41:40 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:20:38 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User coded data point as SOC: Renal and urinary disorders, HLGT: Urinary tract signs and symptoms, HLT: Bladder and urethral symptoms, PT: Urinary retention, LLT: Acute retention of urine - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 19 Jan 2021 12:21:06 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 19 Jan 2021 12:21:06 |
| Data point term sent to Coder | System | 19 Jan 2021 10:01:02 |
| User entered 'Acute Urinary Retention Requiring Coude Foley Catheter' | Kayla Peay (b) (4) (b) (4) | 19 Jan 2021 10:00:53 |

US3722338

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:26:23

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|------------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:20:40 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered 'Yes (Y)' | Kayla Peay (b) (4) (b) (4) | 19 Jan 2021 10:00:53 |

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:26:23

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|------------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:20:42 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered 'No (N)' | Kayla Peay (b) (4) (b) (4) | 19 Jan 2021 10:00:53 |

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:26:23

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|------------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:20:43 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered 'No (N)' | Kayla Peay (b) (4) (b) (4) | 19 Jan 2021 10:00:53 |

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:26:23

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered '14 Oct 2020' | Kayla Peay (b) (4) (b) (4) | 19 Jan 2021 10:00:53 |

US3722338

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:26:23

Start time (00:00-23:59)

| Audit | User | Time (GMT) |
|------------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered empty. | Kayla Peay (b) (4) (b) (4) | 19 Jan 2021 10:00:53 |

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:26:23

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 19 Jan 2021 10:00:53 |

US3722338

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:26:23

[Ongoing?](#)

| Audit | User | Time (GMT) |
|------------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered 'No (N)' | Kayla Peay (b) (4) (b) (4) | 19 Jan 2021 10:00:53 |

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:26:23

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 12 Apr 2021 19:11:48 |
| User closed query 'Please confirm this date as subject had to have this catheter removed and replaced. ' (Site from CRA). | (b) (4), (b) (6) | 22 Mar 2021 16:30:02 |
| Query 'Please confirm this date as subject had to have this catheter removed and replaced. ' answered with 'updated' (Site from CRA). | Marlee Smith (b) (4) | 09 Mar 2021 20:40:43 |
| DataPoint Un-verified. | (b) (4) | |
| User entered '26 Oct 2020' reason for change: Data Entry Error | Marlee Smith (b) (4) | 09 Mar 2021 20:40:37 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| User opened query 'Please confirm this date as subject had to have this catheter removed and replaced. ' (Site from CRA). | (b) (4), (b) (6) | 03 Feb 2021 19:22:42 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered '21 Oct 2020' | Kayla Peay (b) (4) | 19 Jan 2021 10:00:53 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:26:23

End time (00:00-23:59)

| Audit | User | Time (GMT) |
|------------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered empty. | Kayla Peay (b) (4) (b) (4) | 19 Jan 2021 10:00:53 |

US3722338

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:26:23

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 19 Jan 2021 10:00:53 |

US3722338

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:26:23

[Severity](#)

| Audit | User | Time (GMT) |
|--|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered 'Grade 3/Severe (Grade 3/Severe)' | Kayla Peay (b) (4) (b) (4) | 19 Jan 2021 10:00:53 |

US3722338

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:26:23

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|------------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered 'Yes (Y)' | Kayla Peay (b) (4) (b) (4) | 19 Jan 2021 10:00:53 |

US3722338

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:26:23

[Death](#)

| Audit | User | Time (GMT) |
|------------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered '0' | Kayla Peay (b) (4) (b) (4) | 19 Jan 2021 10:00:53 |

US3722338

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:26:23

[Life threatening](#)

| Audit | User | Time (GMT) |
|------------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered '0' | Kayla Peay (b) (4) (b) (4) | 19 Jan 2021 10:00:53 |

US3722338

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:26:23

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|------------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered 'I' | Kayla Peay (b) (4) (b) (4) | 19 Jan 2021 10:00:53 |

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:26:23

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered '12 Oct 2020' | Kayla Peay (b) (4) (b) (4) | 19 Jan 2021 10:00:53 |

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:26:23

Hospital Discharge Date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered '21 Oct 2020' | Kayla Peay (b) (4) (b) (4) | 19 Jan 2021 10:00:53 |

US3722338

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:26:23

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 12 Apr 2021 19:12:01 |
| User closed query 'Per medical records it seems subject was transferred to the ICU after their procedure. if confirmed, please revise.' (Site from CRA). | (b) (4), (b) (6) | 12 Apr 2021 19:12:00 |
| Query 'Per medical records it seems subject was transferred to the ICU after their procedure. if confirmed, please revise.' answered with 'updated' (Site from CRA). | Marlee Smith (b) (4) | 07 Apr 2021 17:14:57 |
| DataPoint Un-verified. | (b) (4) | 07 Apr 2021 17:14:47 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Marlee Smith (b) (4) | 07 Apr 2021 17:14:47 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| User opened query 'Per medical records it seems subject was transferred to the ICU after their procedure. if confirmed, please revise.' (Site from CRA). | (b) (4), (b) (6) | 03 Feb 2021 19:25:27 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered 'No (N)' | Kayla Peay (b) (4) | 19 Jan 2021 10:00:53 |
| | (b) (4) | |

US3722338

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:26:23

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 12 Apr 2021 19:12:03 |
| DataPoint Un-verified. | Marlee Smith (b) (4) | 07 Apr 2021 17:14:47 |
| User entered '2' reason for change: Data Entry Error | (b) (4) | 07 Apr 2021 17:14:47 |
| DataPoint Verified. | Marlee Smith (b) (4) | 07 Apr 2021 17:14:47 |
| DataPoint Verified. | (b) (4) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered empty. | Kayla Peay (b) (4) | 19 Jan 2021 10:00:53 |
| | (b) (4) | |

US3722338

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:26:23

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|------------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered '0' | Kayla Peay (b) (4) (b) (4) | 19 Jan 2021 10:00:53 |

US3722338

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:26:23

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|------------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered '0' | Kayla Peay (b) (4) (b) (4) | 19 Jan 2021 10:00:53 |

US3722338

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:26:23

[Other medically important event](#)

| Audit | User | Time (GMT) |
|------------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered '0' | Kayla Peay (b) (4) (b) (4) | 19 Jan 2021 10:00:53 |

US3722338

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:26:23

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered 'Not Related (NOT RELATED)' | Kayla Peay (b) (4) (b) (4) | 19 Jan 2021 10:00:53 |

US3722338

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:26:23

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered 'Not Related (NOT RELATED)' | Kayla Peay (b) (4) (b) (4) | 19 Jan 2021 10:00:53 |

US3722338

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:26:23

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|--|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered 'Not Applicable (NOT APPLICABLE)' | Kayla Peay (b) (4) (b) (4) | 19 Jan 2021 10:00:53 |

US3722338

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:26:23

[None](#)

| Audit | User | Time (GMT) |
|------------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered '0' | Kayla Peay (b) (4) (b) (4) | 19 Jan 2021 10:00:53 |

US3722338

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:26:23

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|------------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered 'I' | Kayla Peay (b) (4) (b) (4) | 19 Jan 2021 10:00:53 |

US3722338

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:26:23

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|------------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered 'I' | Kayla Peay (b) (4) (b) (4) | 19 Jan 2021 10:00:53 |

US3722338

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:26:23

[Outcome](#)

| Audit | User | Time (GMT) |
|---|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | Kayla Peay (b) (4) (b) (4) | 19 Jan 2021 10:00:53 |

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:26:23

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit | User | Time (GMT) |
|------------------------|-------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered empty. | Kayla Peay (b) (4) (b) (4) | 19 Jan 2021 10:00:53 |

US3722338

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:26:23

[Narrative](#)

| Audit | User | Time (GMT) |
|---|-------------------------------|----------------------|
| Query ' PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'Labs entered, records sent. ' (Site from Safety). DataPoint Un-verified. | Kayla Peay (b) (4) (b) (4) | 04 May 2021 01:47:15 |
| | Kayla Peay (b) (4) (b) (4) | 04 May 2021 01:46:54 |
| User entered 'SUBJECT HOSPITALIZED FOR HERNIA REPAIR. FOLLOWING REPAIR, SUBJECT HAD ACUTE URINARY RETENTION PROLONGING THE STAY. COUDE FOLEY CATHETER WAS PLACED. | Kayla Peay (b) (4) (b) (4) | 04 May 2021 01:46:54 |

10-26

RBC 3.09 4.5-5.9 mil/mm3
Hemoglobin 9.1 12.5-17.5 g/dL
Heatocrit 27.9 41-53%
RDW 16.2 12-16%
Netrophils 8.1 1.4 – 6.6 TH/mm3
Lympocytes .8 1- 3.5 TH/mm3

10-20

HGB 7.7
HCT 23.6

10-21

HGB 7.8

HCT 24.6' reason for change: Data Entry Error

User opened query ' PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).

(b) (4), (b) (6)

25 Apr 2021 17:07:54

US3722338

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:26:23

[Narrative](#)

| Audit | User | Time (GMT) |
|--|------------------------------|----------------------|
| User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety). | (b) (4), (b) (6) | 16 Apr 2021 19:09:41 |
| User closed query 'PV Query: Once obtained, please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342.' (Site from Safety). | (b) (4), (b) (6) | 16 Apr 2021 19:09:39 |
| Query 'PV Query: Once obtained, please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342.' answered with 'Summary has been sent ' (Site from Safety). | Sara Poff (b) (4) (b) (4) | 16 Apr 2021 14:45:27 |
| Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'No results are available ' (Site from Safety). | Sara Poff (b) (4) (b) (4) | 16 Apr 2021 14:45:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |

US3722338

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:26:23

[Narrative](#)

| Audit | User | Time (GMT) |
|--|-------------------------------|----------------------|
| User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety). | (b) (4), (b) (6) | 22 Jan 2021 20:35:50 |
| Query '(AE6) PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' canceled (Site from Safety). | (b) (4), (b) (6) | 22 Jan 2021 20:35:45 |
| User opened query 'PV Query: Once obtained, please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342.' (Site from Safety). | (b) (4), (b) (6) | 22 Jan 2021 20:35:27 |
| User opened query '(AE6) PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety). | (b) (4), (b) (6) | 22 Jan 2021 20:35:20 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered 'Subject hospitalized for hernia repair. Following repair, subject had acute urinary retention prolonging the stay. Coude Foley Catheter was placed.' | Kayla Peay (b) (4) (b) (4) | 19 Jan 2021 10:00:53 |

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:26:23

Serious Adverse Event Derived (CSA Programming Field Only)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 19 Jan 2021 10:00:53 |

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:26:23

Medically Attended AE Derived (CSA Programming Field Only)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 19 Jan 2021 10:00:53 |

US3722338

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 07 Apr 2021 17:14:47 |
| User entered '0' | System | 19 Jan 2021 10:00:53 |

US3722338

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:26:23

[Adverse event](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 22 Mar 2021 16:30:19 |
| User closed query 'Please confirm, if Subclavian Left Sided DVT should be the term per medical records. ' (Site from CRA). | (b) (4), (b) (6) | 22 Mar 2021 16:30:13 |
| User coded data point as SOC: Vascular disorders, HLGT: Embolism and thrombosis, HLT: Peripheral embolism and thrombosis, PT: Deep vein thrombosis, LLT: DVT - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 15 Mar 2021 06:39:55 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 15 Mar 2021 06:39:55 |
| Data point term sent to Coder | System | 18 Feb 2021 15:46:58 |
| Query 'Please confirm, if Subclavian Left Sided DVT should be the term per medical records. ' answered with 'updated' (Site from CRA). | Marlee Smith (b) (4) (b) (4) | 18 Feb 2021 15:46:21 |
| DataPoint Un-verified. | Marlee Smith (b) (4) (b) (4) | 18 Feb 2021 15:46:01 |
| Coding entries removed. | Marlee Smith (b) (4) (b) (4) | 18 Feb 2021 15:46:01 |
| User entered 'Subclavian LEFT SIDED DVT' reason for change: Data Entry Error | Marlee Smith (b) (4) (b) (4) | 18 Feb 2021 15:46:01 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| User opened query 'Please confirm, if Subclavian Left Sided DVT should be the term per medical records. ' (Site from CRA). | (b) (4), (b) (6) | 03 Feb 2021 17:05:23 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User coded data point as SOC: Vascular disorders, HLGT: Embolism and thrombosis, HLT: Peripheral embolism and thrombosis, PT: Deep vein thrombosis, LLT: DVT - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 19 Jan 2021 15:43:07 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 19 Jan 2021 15:43:07 |
| Data point term sent to Coder | System | 19 Jan 2021 15:19:18 |
| User entered 'left sided DVT' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:18:23 |

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:26:23

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|------------------------|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered 'Yes (Y)' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:18:23 |

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:26:23

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|------------------------|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered 'No (N)' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:18:23 |

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:26:23

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|------------------------|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered 'No (N)' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:18:23 |

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:26:23

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered '2 Oct 2020' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:18:23 |

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:26:23

Start time (00:00-23:59)

| Audit | User | Time (GMT) |
|------------------------|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered empty. | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:18:23 |

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:26:23

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 19 Jan 2021 15:18:23 |

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:26:23

[Ongoing?](#)

| Audit | User | Time (GMT) |
|------------------------|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered 'Yes (Y)' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:18:23 |

US3722338

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:26:23

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|------------------------|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered empty. | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:18:23 |

US3722338

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:26:23

End time (00:00-23:59)

| Audit | User | Time (GMT) |
|------------------------|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered empty. | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:18:23 |

US3722338

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:26:23

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 19 Jan 2021 15:18:23 |

US3722338

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:26:23

[Severity](#)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4), (b) (6) | 22 Mar 2021 10:33:40 |
| Query 'Data is required. Please complete.' answered with 'PI to assess' (Site from System). | Marlee Smith (b) (4) | 16 Mar 2021 19:14:06 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:11 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 20 Jan 2021 15:38:52 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 19 Jan 2021 15:18:23 |
| User entered empty. | Marlee Smith (b) (4) | 19 Jan 2021 15:18:23 |
| | (b) (4) | |

US3722338

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:26:23

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|------------------------|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered 'No (N)' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:18:23 |

US3722338

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:26:23

[Death](#)

| Audit | User | Time (GMT) |
|------------------------|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered '0' | Marlee Smith (b) (4) | 19 Jan 2021 15:18:23 |
| | (b) (4) | |

US3722338

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:26:23

[Life threatening](#)

| Audit | User | Time (GMT) |
|------------------------|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered '0' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:18:23 |

US3722338

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:26:23

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|------------------------|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered '0' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:18:23 |

US3722338

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:26:23

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|------------------------|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered empty. | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:18:23 |

US3722338

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:26:23

Hospital Discharge Date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|------------------------|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered empty. | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:18:23 |

US3722338

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:26:23

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|------------------------|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered empty. | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:18:23 |

US3722338

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:26:23

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|------------------------|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered empty. | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:18:23 |

US3722338

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:26:23

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|------------------------|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered '0' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:18:23 |

US3722338

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:26:23

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|------------------------|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered '0' | Marlee Smith (b) (4) | 19 Jan 2021 15:18:23 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:26:23

[Other medically important event](#)

| Audit | User | Time (GMT) |
|------------------------|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered '0' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:18:23 |

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:26:23

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered 'Not Applicable (NOT APPLICABLE)' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:18:23 |

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:26:23

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered 'Not Applicable (NOT APPLICABLE)' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:18:23 |

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:26:23

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered 'None (NONE)' | Marlee Smith (b) (4) | 19 Jan 2021 15:18:23 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:26:23

None

| Audit | User | Time (GMT) |
|------------------------|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered '0' | Marlee Smith (b) (4) | 19 Jan 2021 15:18:23 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:26:23

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|------------------------|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered 'I' | Marlee Smith (b) (4) | 19 Jan 2021 15:18:23 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:26:23

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|------------------------|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered '0' | Marlee Smith (b) (4) | 19 Jan 2021 15:18:23 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:26:23

[Outcome](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:18:23 |

US3722338

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:26:23

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit | User | Time (GMT) |
|------------------------|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered empty. | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:18:23 |

US3722338

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:26:23

[Narrative](#)

| Audit | User | Time (GMT) |
|------------------------|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 19:48:29 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:22 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 16:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 14:46:33 |
| User entered empty. | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:18:23 |

US3722338

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:26:23

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '0' | System | 19 Jan 2021 15:18:23 |

US3722338

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:26:23

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 19 Jan 2021 15:18:23 |

US3722338

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:26:23

[AEID](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 11:59:59 |
| | | |

US3722338

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:26:23

[Adverse event](#)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 11:59:59 |
| User closed query 'Per MM: Please update to the underlying diagnosis, if known.' (Site from DM). | (b) (4), (b) (6) | 29 Apr 2021 17:31:26 |
| Query 'Per MM: Please update to the underlying diagnosis, if known.' answered with 'AE was originally called "hypoxia due to right sided embolism". This was queried and said to split the terms up.' (Site from DM). | Marlee Smith (b) (4) | 28 Apr 2021 12:36:22 |
| User opened query 'Per MM: Please update to the underlying diagnosis, if known.' (Site from DM). | (b) (4), (b) (6) | 24 Apr 2021 14:16:11 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Apr 2021 19:45:32 |
| User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Conditions associated with abnormal gas exchange, PT: Hypoxia, LLT: Hypoxia - version MedDRA\\23.0. | Coder Import (b) (4) | 15 Apr 2021 20:17:09 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 15 Apr 2021 20:17:09 |
| Data point term sent to Coder | System | 15 Apr 2021 20:16:00 |
| User entered 'Hypoxia' | Kayla Peay (b) (4) | 15 Apr 2021 20:15:21 |

US3722338

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:26:23

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 11:59:59 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Apr 2021 19:45:32 |
| User entered 'Yes (Y)' | Kayla Peay (b) (4) (b) (4) | 15 Apr 2021 20:15:21 |

US3722338

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:26:23

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|-----------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 11:59:59 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Apr 2021 19:45:32 |
| User entered 'No (N)' | Kayla Peay (b) (4) (b) (4) | 15 Apr 2021 20:15:21 |

US3722338

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:26:23

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|-----------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 11:59:59 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Apr 2021 19:45:32 |
| User entered 'No (N)' | Kayla Peay (b) (4) (b) (4) | 15 Apr 2021 20:15:21 |

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:26:23

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 11:59:59 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Apr 2021 19:45:32 |
| User entered '26 Oct 2020' | Kayla Peay (b) (4) (b) (4) | 15 Apr 2021 20:15:21 |

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:26:23

Start time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 11:59:59 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Apr 2021 19:45:32 |
| User entered empty. | Kayla Peay (b) (4) (b) (4) | 15 Apr 2021 20:15:21 |

US3722338

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:26:23

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 11:59:59 |
| User entered empty. | System | 15 Apr 2021 20:15:21 |

US3722338

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:26:23

[Ongoing?](#)

| Audit | User | Time (GMT) |
|-----------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 11:59:59 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Apr 2021 19:45:32 |
| User entered 'No (N)' | Kayla Peay (b) (4) (b) (4) | 15 Apr 2021 20:15:21 |

US3722338

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:26:23

If not Ongoing, end date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 11:59:59 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Apr 2021 19:45:32 |
| User entered '28 Oct 2020' | Kayla Peay (b) (4) (b) (4) | 15 Apr 2021 20:15:21 |

US3722338

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:26:23

End time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 11:59:59 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Apr 2021 19:45:32 |
| User entered empty. | Kayla Peay (b) (4) (b) (4) | 15 Apr 2021 20:15:21 |

US3722338

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:26:23

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 11:59:59 |
| User entered empty. | System | 15 Apr 2021 20:15:21 |

US3722338

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:26:23

[Severity](#)

| Audit | User | Time (GMT) |
|--|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 11:59:59 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Apr 2021 19:45:32 |
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' | Kayla Peay (b) (4) (b) (4) | 15 Apr 2021 20:15:21 |

US3722338

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:26:23

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|-----------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 11:59:59 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Apr 2021 19:45:32 |
| User entered 'No (N)' | Kayla Peay (b) (4) (b) (4) | 15 Apr 2021 20:15:21 |

US3722338

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:26:23

[Death](#)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 11:59:59 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Apr 2021 19:45:32 |
| User entered '0' | Kayla Peay (b) (4) (b) (4) | 15 Apr 2021 20:15:21 |

US3722338

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:26:23

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 11:59:59 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Apr 2021 19:45:32 |
| User entered '0' | Kayla Peay (b) (4) (b) (4) | 15 Apr 2021 20:15:21 |

US3722338

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:26:23

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 11:59:59 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Apr 2021 19:45:32 |
| User entered '0' | Kayla Peay (b) (4) (b) (4) | 15 Apr 2021 20:15:21 |

US3722338

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:26:23

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 11:59:59 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Apr 2021 19:45:32 |
| User entered empty. | Kayla Peay (b) (4) (b) (4) | 15 Apr 2021 20:15:21 |

US3722338

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:26:23

Hospital Discharge Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 11:59:59 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Apr 2021 19:45:32 |
| User entered empty. | Kayla Peay (b) (4) (b) (4) | 15 Apr 2021 20:15:21 |

US3722338

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:26:23

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 11:59:59 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Apr 2021 19:45:32 |
| User entered empty. | Kayla Peay (b) (4) (b) (4) | 15 Apr 2021 20:15:21 |

US3722338

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:26:23

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 11:59:59 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Apr 2021 19:45:32 |
| User entered empty. | Kayla Peay (b) (4) (b) (4) | 15 Apr 2021 20:15:21 |

US3722338

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:26:23

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 11:59:59 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Apr 2021 19:45:32 |
| User entered '0' | Kayla Peay (b) (4) (b) (4) | 15 Apr 2021 20:15:21 |

US3722338

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:26:23

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 11:59:59 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Apr 2021 19:45:32 |
| User entered '0' | Kayla Peay (b) (4) (b) (4) | 15 Apr 2021 20:15:21 |

US3722338

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:26:23

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 11:59:59 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Apr 2021 19:45:32 |
| User entered '0' | Kayla Peay (b) (4) (b) (4) | 15 Apr 2021 20:15:21 |

US3722338

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:26:23

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 11:59:59 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Apr 2021 19:45:32 |
| User entered 'Not Related (NOT RELATED)' | Kayla Peay (b) (4) (b) (4) | 15 Apr 2021 20:15:21 |

US3722338

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:26:23

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 11:59:59 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Apr 2021 19:45:32 |
| User entered 'Not Related (NOT RELATED)' | Kayla Peay (b) (4) (b) (4) | 15 Apr 2021 20:15:21 |

US3722338

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:26:23

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 11:59:59 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Apr 2021 19:45:32 |
| User entered 'None (NONE)' | Kayla Peay (b) (4) (b) (4) | 15 Apr 2021 20:15:21 |

US3722338

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:26:23

None

| Audit | User | Time (GMT) |
|---------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 11:59:59 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Apr 2021 19:45:32 |
| User entered '0' | Kayla Peay (b) (4) (b) (4) | 15 Apr 2021 20:15:21 |

US3722338

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:26:23

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 11:59:59 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Apr 2021 19:45:32 |
| User entered 'I' | Kayla Peay (b) (4) (b) (4) | 15 Apr 2021 20:15:21 |

US3722338

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:26:23

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 11:59:59 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Apr 2021 19:45:32 |
| User entered '0' | Kayla Peay (b) (4) (b) (4) | 15 Apr 2021 20:15:21 |

US3722338

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:26:23

[Outcome](#)

| Audit | User | Time (GMT) |
|---|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 11:59:59 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Apr 2021 19:45:32 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | Kayla Peay (b) (4) (b) (4) | 15 Apr 2021 20:15:21 |

US3722338

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:26:23

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit | User | Time (GMT) |
|---------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 11:59:59 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Apr 2021 19:45:32 |
| User entered empty. | Kayla Peay (b) (4) (b) (4) | 15 Apr 2021 20:15:21 |

US3722338

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:26:23

[Narrative](#)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 11:59:59 |
| DataPoint Verified. | (b) (4), (b) (6) | 22 Apr 2021 19:45:32 |
| User entered empty. | Kayla Peay (b) (4) (b) (4) | 15 Apr 2021 20:15:21 |

US3722338

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:26:23

Serious Adverse Event Derived (CSA Programming Field Only)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 11:59:59 |
| User entered '0' | System | 15 Apr 2021 20:15:21 |

US3722338

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:26:23

Medically Attended AE Derived (CSA Programming Field Only)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 11:59:59 |
| User entered 'I' | System | 15 Apr 2021 20:15:21 |

US3722338

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 11:59:59 |
| | | |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|---|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 10:26:35 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:42:04 |
| User closed query 'Per ETRTR: Please confirm no medication was dosed for SAE "Hernia Repair", even at hospitalization. Update ConMeds and AE CRF otherwise, thanks.' (Site from CRA). | (b) (4), (b) (6) | 15 Nov 2020 21:08:41 |
| Query 'Per ETRTR: Please confirm no medication was dosed for SAE "Hernia Repair", even at hospitalization. Update ConMeds and AE CRF otherwise, thanks.' answered with 'Subject is lost to follow up therefore unable to confirm.' (Site from CRA). | Sara Poff (b) (4) (b) (4) | 10 Nov 2020 21:58:42 |
| User opened query 'Per ETRTR: Please confirm no medication was dosed for SAE "Hernia Repair", even at hospitalization. Update ConMeds and AE CRF otherwise, thanks.' (Site from CRA). | (b) (4), (b) (6) | 27 Oct 2020 22:47:45 |
| User entered 'Yes (Y)' | Kayla Peay (b) (4) (b) (4) | 20 Aug 2020 17:37:43 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:26:23

Name of Medication

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User closed query 'Per medical records, subject started Klonopin 1mg HQ starting 3/17/20. Please update con-meds.' (Site from CRA). | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 19:19:03 |
| Query 'Per medical records, subject started Klonopin 1mg HQ starting 3/17/20. Please update con-meds.' answered with 'updated' (Site from CRA). | Marlee Smith (b) (4) (b) (4) | 08 Apr 2021 15:43:25 |
| User opened query 'Per medical records, subject started Klonopin 1mg HQ starting 3/17/20. Please update con-meds.' (Site from CRA). | (b) (4), (b) (6) | 08 Apr 2021 15:40:00 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN LISPRO, PRODUCTSYNONYM: HUMALOG - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 21 Aug 2020 05:26:17 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 21 Aug 2020 05:26:17 |
| Data point term sent to Coder | System | 20 Aug 2020 17:38:35 |
| User entered 'humalog' | Kayla Peay (b) (4) (b) (4) | 20 Aug 2020 17:38:24 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:26:23

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'No (N)' | Kayla Peay (b) (4) (b) (4) | 20 Aug 2020 17:38:24 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:26:23

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'diabetes 2' | Kayla Peay (b) (4) (b) (4) | 20 Aug 2020 17:38:24 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:26:23

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered '20' | Kayla Peay (b) (4) (b) (4) | 20 Aug 2020 17:38:24 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:26:23

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'IU (IU)' | Kayla Peay (b) (4) (b) (4) | 20 Aug 2020 17:38:24 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:26:23

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered empty. | Kayla Peay (b) (4) (b) (4) | 20 Aug 2020 17:38:24 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:26:23

[Frequency](#)

| Audit | User | Time (GMT) |
|---|-------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'four times daily (QID)' reason for change: Data Entry Error | Amy Ford (b) (4) (b) (4) | 25 Sep 2020 15:44:33 |
| User entered 'other (OTHER)' | Kayla Peay (b) (4) (b) (4) | 20 Aug 2020 17:38:24 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:26:23

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---|-------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User closed query 'Per CDM: Please note that "Four times daily" is an available option for Frequency. Kindly update frequency field as appropriate and remove "QID" in If frequency is Other, specify ' (Site from DM). | (b) (4), (b) (6) | 25 Sep 2020 19:33:34 |
| Query 'Per CDM: Please note that "Four times daily" is an available option for Frequency. Kindly update frequency field as appropriate and remove "QID" in If frequency is Other, specify ' answered with 'updated' (Site from DM). | Amy Ford (b) (4) (b) (4) | 25 Sep 2020 15:44:39 |
| User entered empty; reason for change Data Entry Error | Amy Ford (b) (4) (b) (4) | 25 Sep 2020 15:44:33 |
| User opened query 'Per CDM: Please note that "Four times daily" is an available option for Frequency. Kindly update frequency field as appropriate and remove "QID" in If frequency is Other, specify ' (Site from DM). | (b) (4), (b) (6) | 31 Aug 2020 10:01:58 |
| User entered 'QID' | Kayla Peay (b) (4) (b) (4) | 20 Aug 2020 17:38:24 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:26:23

[Route of administration](#)

| Audit | User | Time (GMT) |
|--|-------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'Subcutaneous (SUBCUTANEOUS)' | Kayla Peay (b) (4) (b) (4) | 20 Aug 2020 17:38:24 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:26:23

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered empty. | Kayla Peay (b) (4) (b) (4) | 20 Aug 2020 17:38:24 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:26:23

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|-------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 15:46:01 |
| Query 'Please verify start date, as this med was not approved at this time.' canceled (Site from CRA). | (b) (4), (b) (6) | 08 Apr 2021 15:45:58 |
| User opened query 'Please verify start date, as this med was not approved at this time.' (Site from CRA). | (b) (4), (b) (6) | 08 Apr 2021 15:44:57 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 08 Apr 2021 15:43:47 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| Amendment Manager: Query closed during migration process because the edit check no longer exists in target version. | System | 21 Aug 2020 05:53:16 |
| 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 | 20 Aug 2020 17:38:24 |
| User entered 'un UNK 1994' | Kayla Peay (b) (4) (b) (4) | 20 Aug 2020 17:38:24 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:26:23

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered '0' | Kayla Peay (b) (4) (b) (4) | 20 Aug 2020 17:38:24 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:26:23

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'Yes (Y)' | Kayla Peay (b) (4) (b) (4) | 20 Aug 2020 17:38:24 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:26:23

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered empty. | Kayla Peay (b) (4) (b) (4) | 20 Aug 2020 17:38:24 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:26:23

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'No (N)' | Kayla Peay (b) (4) (b) (4) | 20 Aug 2020 17:38:24 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:26:23

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '4' | System | 25 Sep 2020 15:44:33 |
| User entered empty. | System | 20 Aug 2020 17:38:24 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:26:23

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '1' | System | 25 Sep 2020 15:44:33 |
| User entered empty. | System | 20 Aug 2020 17:38:24 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:26:23

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 25 Sep 2020 15:44:33 |
| User entered empty. | System | 20 Aug 2020 17:38:24 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:26:23

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|---|--|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING, PRODUCT: INSULIN GLARGINE, PRODUCTSYNONYM: LANTUS - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 20 Aug 2020 17:41:35 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 20 Aug 2020 17:41:35 |
| Data point term sent to Coder User entered 'lantus' | System Kayla Peay (b) (4) (b) (4) | 20 Aug 2020 17:39:36 20 Aug 2020 17:38:58 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:26:23

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'No (N)' | Kayla Peay (b) (4) (b) (4) | 20 Aug 2020 17:38:58 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:26:23

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'diabetes 2' | Kayla Peay (b) (4) (b) (4) | 20 Aug 2020 17:38:58 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:26:23

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered '70' | Kayla Peay (b) (4) (b) (4) | 20 Aug 2020 17:38:58 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:26:23

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'IU (IU)' | Kayla Peay (b) (4) (b) (4) | 20 Aug 2020 17:38:58 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:26:23

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered empty. | Kayla Peay (b) (4) (b) (4) | 20 Aug 2020 17:38:58 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:26:23

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|-------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'once daily (QD)' | Kayla Peay (b) (4) (b) (4) | 20 Aug 2020 17:38:58 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:26:23

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered empty. | Kayla Peay (b) (4) (b) (4) | 20 Aug 2020 17:38:58 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:26:23

[Route of administration](#)

| Audit | User | Time (GMT) |
|--|-------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'Subcutaneous (SUBCUTANEOUS)' | Kayla Peay (b) (4) (b) (4) | 20 Aug 2020 17:38:58 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:26:23

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered empty. | Kayla Peay (b) (4) (b) (4) | 20 Aug 2020 17:38:58 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:26:23

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|-------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| Amendment Manager: Query closed during migration process because the edit check no longer exists in target version. | System | 21 Aug 2020 05:53:16 |
| 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 | 20 Aug 2020 17:38:58 |
| User entered 'un UNK 1993' | Kayla Peay (b) (4) (b) (4) | 20 Aug 2020 17:38:58 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:26:23

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered '0' | Kayla Peay (b) (4) (b) (4) | 20 Aug 2020 17:38:58 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:26:23

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'Yes (Y)' | Kayla Peay (b) (4) (b) (4) | 20 Aug 2020 17:38:58 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:26:23

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered empty. | Kayla Peay (b) (4) (b) (4) | 20 Aug 2020 17:38:58 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:26:23

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'No (N)' | Kayla Peay (b) (4) (b) (4) | 20 Aug 2020 17:38:58 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:26:23

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 20 Aug 2020 17:38:58 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:26:23

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 20 Aug 2020 17:38:58 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:26:23

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 20 Aug 2020 17:38:58 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:26:23

Name of Medication

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: COMBINATIONS OF ORAL BLOOD GLUCOSE LOWERING DRUGS, PRODUCT: EMPAGLIFLOZIN;METFORMIN HYDROCHLORIDE, PRODUCTSYNONYM: SYNJARDY - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 20 Aug 2020 17:41:35 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 20 Aug 2020 17:41:35 |
| Data point term sent to Coder | System | 20 Aug 2020 17:39:37 |
| User entered 'synjardy' | Kayla Peay (b) (4) (b) (4) | 20 Aug 2020 17:39:32 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:26:23

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'No (N)' | Kayla Peay (b) (4) (b) (4) | 20 Aug 2020 17:39:32 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:26:23

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'diabetes 2' | Kayla Peay (b) (4) (b) (4) | 20 Aug 2020 17:39:32 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:26:23

[Dose per administration](#)

| Audit | User | Time (GMT) |
|--|-------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User closed query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 12.5/1000).' (Site from DM). | (b) (4), (b) (6) | 11 Nov 2020 06:30:10 |
| Query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 12.5/1000).' answered with 'Updated' (Site from DM). | Sara Poff (b) (4) (b) (4) | 10 Nov 2020 21:57:30 |
| User entered '5/1000' reason for change: Data Entry Error | Sara Poff (b) (4) (b) (4) | 10 Nov 2020 21:57:22 |
| User opened query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 12.5/1000).' (Site from DM). | (b) (4), (b) (6) | 05 Oct 2020 09:29:00 |
| User entered '2000' | Kayla Peay (b) (4) (b) (4) | 20 Aug 2020 17:39:32 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:26:23

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'mg (mg)' | Kayla Peay (b) (4) (b) (4) | 20 Aug 2020 17:39:32 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:26:23

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered empty. | Kayla Peay (b) (4) (b) (4) | 20 Aug 2020 17:39:32 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:26:23

[Frequency](#)

| Audit | User | Time (GMT) |
|---|-------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'twice daily (BID)' reason for change: Data Entry Error | Sara Poff (b) (4) (b) (4) | 10 Nov 2020 21:57:22 |
| User entered 'once daily (QD)' | Kayla Peay (b) (4) (b) (4) | 20 Aug 2020 17:39:32 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:26:23

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered empty. | Kayla Peay (b) (4) (b) (4) | 20 Aug 2020 17:39:32 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:26:23

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'Oral (ORAL)' | Kayla Peay (b) (4) (b) (4) | 20 Aug 2020 17:39:32 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:26:23

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered empty. | Kayla Peay (b) (4) (b) (4) | 20 Aug 2020 17:39:32 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:26:23

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|-------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| Amendment Manager: Query closed during migration process because the edit check no longer exists in target version. | System | 21 Aug 2020 05:53:16 |
| 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 | 20 Aug 2020 17:39:32 |
| User entered 'un UNK 2018' | Kayla Peay (b) (4) (b) (4) | 20 Aug 2020 17:39:32 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:26:23

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered '0' | Kayla Peay (b) (4) (b) (4) | 20 Aug 2020 17:39:32 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:26:23

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'Yes (Y)' | Kayla Peay (b) (4) (b) (4) | 20 Aug 2020 17:39:32 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:26:23

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered empty. | Kayla Peay (b) (4) (b) (4) | 20 Aug 2020 17:39:32 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:26:23

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'No (N)' | Kayla Peay (b) (4) (b) (4) | 20 Aug 2020 17:39:32 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:26:23

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '2' | System | 10 Nov 2020 21:57:22 |
| User entered '1' | System | 20 Aug 2020 17:39:32 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:26:23

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 20 Aug 2020 17:39:32 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:26:23

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 20 Aug 2020 17:39:32 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:26:23

Name of Medication

| Audit | User | Time (GMT) |
|---|---|--|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 20 Aug 2020 17:41:36 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 20 Aug 2020 17:41:36 |
| Data point term sent to Coder User entered 'lisinopril' | System Kayla Peay (b) (4) (b) (4) | 20 Aug 2020 17:40:37 20 Aug 2020 17:40:05 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:26:23

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'No (N)' | Kayla Peay (b) (4) (b) (4) | 20 Aug 2020 17:40:05 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:26:23

[Indication](#)

| Audit | User | Time (GMT) |
|-----------------------------|-------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'hypertension' | Kayla Peay (b) (4) (b) (4) | 20 Aug 2020 17:40:05 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:26:23

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered '20' | Kayla Peay (b) (4) (b) (4) | 20 Aug 2020 17:40:05 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:26:23

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'mg (mg)' | Kayla Peay (b) (4) (b) (4) | 20 Aug 2020 17:40:05 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:26:23

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered empty. | Kayla Peay (b) (4) (b) (4) | 20 Aug 2020 17:40:05 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:26:23

[Frequency](#)

| Audit | User | Time (GMT) |
|----------------------------------|-------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'twice daily (BID)' | Kayla Peay (b) (4) (b) (4) | 20 Aug 2020 17:40:05 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:26:23

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered empty. | Kayla Peay (b) (4) (b) (4) | 20 Aug 2020 17:40:05 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:26:23

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'Oral (ORAL)' | Kayla Peay (b) (4) (b) (4) | 20 Aug 2020 17:40:05 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:26:23

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered empty. | Kayla Peay (b) (4) (b) (4) | 20 Aug 2020 17:40:05 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:26:23

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|-------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| Amendment Manager: Query closed during migration process because the edit check no longer exists in target version. | System | 21 Aug 2020 05:53:16 |
| 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 | 20 Aug 2020 17:40:05 |
| User entered 'un UNK 2017' | Kayla Peay (b) (4) (b) (4) | 20 Aug 2020 17:40:05 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:26:23

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered '0' | Kayla Peay (b) (4) (b) (4) | 20 Aug 2020 17:40:05 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:26:23

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'Yes (Y)' | Kayla Peay (b) (4) (b) (4) | 20 Aug 2020 17:40:05 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:26:23

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered empty. | Kayla Peay (b) (4) (b) (4) | 20 Aug 2020 17:40:05 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:26:23

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'No (N)' | Kayla Peay (b) (4) (b) (4) | 20 Aug 2020 17:40:05 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:26:23

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '2' | System | 20 Aug 2020 17:40:05 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:26:23

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 20 Aug 2020 17:40:05 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:26:23

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 20 Aug 2020 17:40:05 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:26:23

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: PRAVASTATIN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 20 Aug 2020 17:41:35 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 20 Aug 2020 17:41:35 |
| Data point term sent to Coder | System | 20 Aug 2020 17:40:38 |
| User entered 'pravastatin' | Kayla Peay (b) (4) (b) (4) | 20 Aug 2020 17:40:35 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:26:23

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'No (N)' | Kayla Peay (b) (4) (b) (4) | 20 Aug 2020 17:40:35 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:26:23

[Indication](#)

| Audit | User | Time (GMT) |
|-------------------------------|-------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'hyperlipidemia' | Kayla Peay (b) (4) (b) (4) | 20 Aug 2020 17:40:35 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:26:23

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered '10' | Kayla Peay (b) (4) (b) (4) | 20 Aug 2020 17:40:35 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:26:23

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'mg (mg)' | Kayla Peay (b) (4) (b) (4) | 20 Aug 2020 17:40:35 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:26:23

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered empty. | Kayla Peay (b) (4) (b) (4) | 20 Aug 2020 17:40:35 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:26:23

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|-------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'once daily (QD)' | Kayla Peay (b) (4) (b) (4) | 20 Aug 2020 17:40:35 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:26:23

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered empty. | Kayla Peay (b) (4) (b) (4) | 20 Aug 2020 17:40:35 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:26:23

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'Oral (ORAL)' | Kayla Peay (b) (4) (b) (4) | 20 Aug 2020 17:40:35 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:26:23

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered empty. | Kayla Peay (b) (4) (b) (4) | 20 Aug 2020 17:40:35 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:26:23

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|-------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| Amendment Manager: Query closed during migration process because the edit check no longer exists in target version. | System | 21 Aug 2020 05:53:16 |
| 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 | 20 Aug 2020 17:40:35 |
| User entered 'un UNK 2017' | Kayla Peay (b) (4) (b) (4) | 20 Aug 2020 17:40:35 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:26:23

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered '0' | Kayla Peay (b) (4) (b) (4) | 20 Aug 2020 17:40:35 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:26:23

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'Yes (Y)' | Kayla Peay (b) (4) (b) (4) | 20 Aug 2020 17:40:35 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:26:23

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered empty. | Kayla Peay (b) (4) (b) (4) | 20 Aug 2020 17:40:35 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:26:23

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'No (N)' | Kayla Peay (b) (4) (b) (4) | 20 Aug 2020 17:40:35 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:26:23

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 20 Aug 2020 17:40:35 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:26:23

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 20 Aug 2020 17:40:35 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:26:23

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 20 Aug 2020 17:40:35 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:26:23

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:41 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: SALICYLIC ACID AND DERIVATIVES, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 25 Sep 2020 19:24:46 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 25 Sep 2020 19:24:46 |
| Data point term sent to Coder | System | 25 Sep 2020 15:46:39 |
| User entered 'Aspirin' | Amy Ford (b) (4) (b) (4) | 25 Sep 2020 15:46:19 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:26:23

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:41 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'No (N)' | Amy Ford (b) (4) | 25 Sep 2020 15:46:19 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:26:23

[Indication](#)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:41 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'left arm pain and swelling' | Amy Ford (b) (4) | 25 Sep 2020 15:46:19 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:26:23

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:41 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered '325' | Amy Ford (b) (4) | 25 Sep 2020 15:46:19 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:26:23

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:41 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'mg (mg)' | Amy Ford (b) (4) (b) (4) | 25 Sep 2020 15:46:19 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:26:23

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:41 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered empty. | Amy Ford (b) (4) | 25 Sep 2020 15:46:19 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:26:23

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:41 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'as needed (PRN)' | Amy Ford (b) (4) (b) (4) | 25 Sep 2020 15:46:19 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:26:23

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:41 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered empty. | Amy Ford (b) (4) | 25 Sep 2020 15:46:19 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:26:23

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:41 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'Oral (ORAL)' | Amy Ford (b) (4) (b) (4) | 25 Sep 2020 15:46:19 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:26:23

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:41 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered empty. | Amy Ford (b) (4) (b) (4) | 25 Sep 2020 15:46:19 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:26:23

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:41 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered '19 Sep 2020' | Amy Ford (b) (4) (b) (4) | 25 Sep 2020 15:46:19 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:26:23

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:41 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered '0' | Amy Ford (b) (4) | 25 Sep 2020 15:46:19 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:26:23

[Ongoing?](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:41 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 15:18:55 |
| User closed query 'Per DM CLR: Please note, the corresponding AE has resolved. However, this medication is still ongoing. Please reconcile AE/CM dates and update as appropriate. Otherwise, clarify continued use after AE resolution.' (Site from DM). | (b) (4), (b) (6) | 05 Mar 2021 12:54:26 |
| Query 'Per DM CLR: Please note, the corresponding AE has resolved. However, this medication is still ongoing. Please reconcile AE/CM dates and update as appropriate. Otherwise, clarify continued use after AE resolution.' answered with 'updated' (Site from DM). | Marlee Smith (b) (4) (b) (4) | 04 Mar 2021 16:03:24 |
| DataPoint Un-verified. | Marlee Smith (b) (4) (b) (4) | 04 Mar 2021 16:03:14 |
| User entered 'No (N)' reason for change: Data Entry Error | Marlee Smith (b) (4) (b) (4) | 04 Mar 2021 16:03:14 |
| User opened query 'Per DM CLR: Please note, the corresponding AE has resolved. However, this medication is still ongoing. Please reconcile AE/CM dates and update as appropriate. Otherwise, clarify continued use after AE resolution.' (Site from DM). | (b) (4), (b) (6) | 27 Jan 2021 17:50:46 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'Yes (Y)' | Amy Ford (b) (4) (b) (4) | 25 Sep 2020 15:46:19 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:26:23

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:41 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 15:18:55 |
| DataPoint Un-verified. | Marlee Smith (b) (4) | 04 Mar 2021 16:03:14 |
| User entered '23 Sep 2020' reason for change: Data Entry Error | (b) (4) Marlee Smith (b) (4) | 04 Mar 2021 16:03:14 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered empty. | Amy Ford (b) (4) (b) (4) | 25 Sep 2020 15:46:19 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:26:23

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:41 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'Yes (Y)' | Amy Ford (b) (4) | 25 Sep 2020 15:46:19 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:26:23

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:41 |
| User entered empty. | System | 25 Sep 2020 15:46:19 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:26:23

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:41 |
| User entered empty. | System | 25 Sep 2020 15:46:19 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:26:23

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:41 |
| User entered empty. | System | 25 Sep 2020 15:46:19 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:26:23

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:43 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| 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) | 27 Sep 2020 09:33:40 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 27 Sep 2020 09:33:40 |
| Data point term sent to Coder | System | 25 Sep 2020 15:47:48 |
| User entered 'Ibuprofen' | Amy Ford (b) (4) (b) (4) | 25 Sep 2020 15:47:06 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:26:23

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:43 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'No (N)' | Amy Ford (b) (4) | 25 Sep 2020 15:47:06 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:26:23

[Indication](#)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:43 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'left arm pain and swelling' | Amy Ford (b) (4) | 25 Sep 2020 15:47:06 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:26:23

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:43 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered '200' | Amy Ford (b) (4) (b) (4) | 25 Sep 2020 15:47:06 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:26:23

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:43 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'mg (mg)' | Amy Ford (b) (4) (b) (4) | 25 Sep 2020 15:47:06 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:26:23

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:43 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered empty. | Amy Ford (b) (4) | 25 Sep 2020 15:47:06 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:26:23

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:43 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'as needed (PRN)' | Amy Ford (b) (4) | 25 Sep 2020 15:47:06 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:26:23

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:43 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered empty. | Amy Ford (b) (4) | 25 Sep 2020 15:47:06 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:26:23

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:43 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'Oral (ORAL)' | Amy Ford (b) (4) | 25 Sep 2020 15:47:06 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:26:23

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:43 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered empty. | Amy Ford (b) (4) | 25 Sep 2020 15:47:06 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:26:23

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:43 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 15:18:55 |
| DataPoint Un-verified. | Marlee Smith (b) (4) | 09 Mar 2021 20:02:22 |
| User entered '19 Sep 2020' reason for change: Data Entry Error | (b) (4) Marlee Smith (b) (4) | 09 Mar 2021 20:02:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered '24 Sep 2020' | Amy Ford (b) (4) (b) (4) | 25 Sep 2020 15:47:06 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:26:23

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:43 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered '0' | Amy Ford (b) (4) | 25 Sep 2020 15:47:06 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:26:23

[Ongoing?](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:43 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 15:18:55 |
| User closed query 'Per DM CLR: Please note, the corresponding AE has resolved. However, this medication is still ongoing. Please reconcile AE/CM dates and update as appropriate. Otherwise, clarify continued use after AE resolution.' (Site from DM). | (b) (4), (b) (6) | 11 Mar 2021 12:42:28 |
| Query 'Per DM CLR: Please note, the corresponding AE has resolved. However, this medication is still ongoing. Please reconcile AE/CM dates and update as appropriate. Otherwise, clarify continued use after AE resolution.' answered with 'updated' (Site from DM). | Marlee Smith (b) (4) (b) (4) | 09 Mar 2021 20:02:30 |
| DataPoint Un-verified. | Marlee Smith (b) (4) (b) (4) | 09 Mar 2021 20:02:22 |
| User entered 'No (N)' reason for change: Data Entry Error | Marlee Smith (b) (4) (b) (4) | 09 Mar 2021 20:02:22 |
| User opened query 'Per DM CLR: Please note, the corresponding AE has resolved. However, this medication is still ongoing. Please reconcile AE/CM dates and update as appropriate. Otherwise, clarify continued use after AE resolution.' (Site from DM). | (b) (4), (b) (6) | 27 Jan 2021 17:50:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'Yes (Y)' | Amy Ford (b) (4) (b) (4) | 25 Sep 2020 15:47:06 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:26:23

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:43 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 15:18:55 |
| DataPoint Un-verified. | Marlee Smith (b) (4) | 09 Mar 2021 20:02:22 |
| User entered '23 Sep 2020' reason for change: Data Entry Error | (b) (4) Marlee Smith (b) (4) | 09 Mar 2021 20:02:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered empty. | Amy Ford (b) (4) (b) (4) | 25 Sep 2020 15:47:06 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:26:23

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:43 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'Yes (Y)' | Amy Ford (b) (4) | 25 Sep 2020 15:47:06 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:26:23

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:43 |
| User entered empty. | System | 25 Sep 2020 15:47:06 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:26:23

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:43 |
| User entered empty. | System | 25 Sep 2020 15:47:06 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:26:23

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:43 |
| User entered empty. | System | 25 Sep 2020 15:47:06 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:26:23

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:44:13 |
| User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: RIVAROXABAN, PRODUCTSYNONYM: XARELTO - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 19 Jan 2021 15:06:06 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 19 Jan 2021 15:06:06 |
| Data point term sent to Coder | System | 19 Jan 2021 15:04:56 |
| User entered 'Xarelto' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:04:53 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:26:23

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:44:27 |
| User entered 'No (N)' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:04:53 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:26:23

[Indication](#)

| Audit | User | Time (GMT) |
|-------------------------------|---------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:44:15 |
| User entered 'Left sided DVT' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:04:53 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:26:23

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:44:17 |
| User entered '20' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:04:53 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:26:23

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:44:19 |
| User entered 'mg (mg)' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:04:53 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:26:23

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:44:21 |
| User entered empty. | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:04:53 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:26:23

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|---------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:44:23 |
| User entered 'once daily (QD)' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:04:53 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:26:23

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:44:25 |
| User entered empty. | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:04:53 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:26:23

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:44:31 |
| User entered 'Oral (ORAL)' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:04:53 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:26:23

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) | 20 Jan 2021 15:44:42 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 20 Jan 2021 15:44:38 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:44:35 |
| User entered empty. | Marlee Smith (b) (4) | 19 Jan 2021 15:04:53 |
| | (b) (4) | |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:26:23

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:44:44 |
| User entered '02 Oct 2020' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:04:53 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:26:23

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:44:45 |
| User entered '0' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:04:53 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:26:23

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:44:48 |
| User entered 'Yes (Y)' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:04:53 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:26:23

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:44:50 |
| User entered empty. | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:04:53 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:26:23

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 15:18:55 |
| User closed query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,). Please review and update as appropriate. Otherwise, provide clarification. ' (Site from DM). | (b) (4), (b) (6) | 05 Mar 2021 12:51:37 |
| Query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,). Please review and update as appropriate. Otherwise, provide clarification. ' answered with 'updated' (Site from DM). | Marlee Smith (b) (4) (b) (4) | 03 Mar 2021 19:48:31 |
| DataPoint Un-verified. | Marlee Smith (b) (4) (b) (4) | 03 Mar 2021 19:48:25 |
| User entered 'No (N)' reason for change: Data Entry Error | Marlee Smith (b) (4) (b) (4) | 03 Mar 2021 19:48:25 |
| User opened query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,). Please review and update as appropriate. Otherwise, provide clarification. ' (Site from DM). | (b) (4), (b) (6) | 21 Feb 2021 10:09:06 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:26:23

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|------------------------|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:44:52 |
| User entered 'Yes (Y)' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:04:53 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:26:23

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 19 Jan 2021 15:04:53 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:26:23

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 19 Jan 2021 15:04:53 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:26:23

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 19 Jan 2021 15:04:53 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:26:23

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:46 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:45:45 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROMORPHONE HYDROCHLORIDE, PRODUCTSYNONYM: DILAUDID - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 19 Jan 2021 15:07:06 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 19 Jan 2021 15:07:06 |
| Data point term sent to Coder | System | 19 Jan 2021 15:05:56 |
| User entered 'dilaudid' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:05:50 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:26:23

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:46 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:45:51 |
| User entered 'No (N)' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:05:50 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:26:23

[Indication](#)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:46 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:45:53 |
| User entered 'pain related to acute incarcerated left hernia repair with mesh' | Marlee Smith (b) (4) | 19 Jan 2021 15:05:50 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:26:23

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:46 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:45:55 |
| User entered '4' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:05:50 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:26:23

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:46 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:45:57 |
| User entered 'mg (mg)' | Marlee Smith (b) (4) | 19 Jan 2021 15:05:50 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:26:23

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:46 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered empty. | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:05:50 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:26:23

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:46 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'as needed (PRN)' | Marlee Smith (b) (4) | 19 Jan 2021 15:05:50 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:26:23

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:46 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered empty. | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:05:50 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:26:23

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:46 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'Oral (ORAL)' | Marlee Smith (b) (4) | 19 Jan 2021 15:05:50 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:26:23

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:46 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered empty. | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:05:50 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:26:23

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:46 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User closed query 'Please reconcile against medical records as it seems this was ordered on 28Oct2020 with anticipated end date on 03Nov2020. Please review and update as needed or clarify otherwise.' (Site from CRA). | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 15:18:11 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 15:18:08 |
| Query 'Please reconcile against medical records as it seems this was ordered on 28Oct2020 with anticipated end date on 03Nov2020. Please review and update as needed or clarify otherwise.' answered with 'updated' (Site from CRA). | Marlee Smith (b) (4) (b) (4) | 07 Apr 2021 15:56:15 |
| DataPoint Un-verified. | Marlee Smith (b) (4) (b) (4) | 07 Apr 2021 15:56:10 |
| User entered '28 Oct 2020' reason for change: Data Entry Error | Marlee Smith (b) (4) (b) (4) | 07 Apr 2021 15:56:10 |
| User opened query 'Please reconcile against medical records as it seems this was ordered on 28Oct2020 with anticipated end date on 03Nov2020. Please review and update as needed or clarify otherwise.' (Site from CRA). | (b) (4), (b) (6) | 03 Feb 2021 18:06:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered '12 Oct 2020' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:05:50 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:26:23

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:46 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered '0' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:05:50 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:26:23

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:46 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'No (N)' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:05:50 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:26:23

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:46 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 15:18:55 |
| DataPoint Un-verified. | Marlee Smith (b) (4) | 07 Apr 2021 15:56:10 |
| User entered '03 Nov 2020' reason for change: Data Entry Error | (b) (4) Marlee Smith (b) (4) | 07 Apr 2021 15:56:10 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered '21 Oct 2020' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:05:50 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:26:23

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:46 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Mar 2021 16:31:19 |
| User closed query 'Please confirm, this does not seem to be a solicited event.' (Site from CRA). | (b) (4), (b) (6) | 22 Mar 2021 16:31:17 |
| Query 'Please confirm, this does not seem to be a solicited event.' answered with 'updated' (Site from CRA). | Marlee Smith (b) (4) (b) (4) | 03 Mar 2021 19:48:50 |
| DataPoint Un-verified. | Marlee Smith (b) (4) (b) (4) | 03 Mar 2021 19:48:42 |
| User entered 'No (N)' reason for change: Data Entry Error | Marlee Smith (b) (4) (b) (4) | 03 Mar 2021 19:48:42 |
| User opened query 'Please confirm, this does not seem to be a solicited event.' (Site from CRA). | (b) (4), (b) (6) | 03 Feb 2021 18:06:45 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'Yes (Y)' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:05:50 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:26:23

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:46 |
| User entered empty. | System | 19 Jan 2021 15:05:50 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:26:23

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:46 |
| User entered empty. | System | 19 Jan 2021 15:05:50 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:26:23

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:46 |
| User entered empty. | System | 19 Jan 2021 15:05:50 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:26:23

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:48 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OPIOID ANESTHETICS, PRODUCT: FENTANYL - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 19 Jan 2021 23:09:10 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 19 Jan 2021 23:09:10 |
| Data point term sent to Coder | System | 19 Jan 2021 15:06:58 |
| User entered 'fentanyl' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:06:32 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:26:23

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:48 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'No (N)' | Marlee Smith (b) (4) | 19 Jan 2021 15:06:32 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:26:23

[Indication](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:48 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'pain related to acute incarcerated left hernia repair with mesh' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:06:32 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:26:23

[Dose per administration](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:48 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 15:18:55 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4), (b) (6) | 11 Mar 2021 12:42:55 |
| Query 'Data is required. Please complete.' answered with 'Unknown, not in medical records' (Site from System). | Marlee Smith (b) (4) (b) (4) | 09 Mar 2021 18:14:10 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 20 Jan 2021 15:47:21 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 19 Jan 2021 15:06:32 |
| User entered empty. | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:06:32 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:26:23

[Dose unit](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:48 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 15:18:55 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4), (b) (6) | 11 Mar 2021 12:42:57 |
| Query 'Data is required. Please complete.' answered with 'Unknown, not in medical records' (Site from System). | Marlee Smith (b) (4) (b) (4) | 09 Mar 2021 18:14:15 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 20 Jan 2021 15:49:29 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 19 Jan 2021 15:06:32 |
| User entered empty. | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:06:32 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:26:23

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:48 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 15:18:55 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 20 Jan 2021 15:49:26 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered empty. | Marlee Smith (b) (4) | 19 Jan 2021 15:06:32 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:26:23

[Frequency](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:48 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 15:18:55 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4), (b) (6) | 11 Mar 2021 12:42:59 |
| Query 'Data is required. Please complete.' answered with 'Unknown, not in medical records' (Site from System). | Marlee Smith (b) (4) (b) (4) | 09 Mar 2021 18:14:19 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 20 Jan 2021 15:49:23 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 19 Jan 2021 15:06:32 |
| User entered empty. | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:06:32 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:26:23

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:48 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:49:19 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 20 Jan 2021 15:49:17 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered empty. | Marlee Smith (b) (4) | 19 Jan 2021 15:06:32 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:26:23

[Route of administration](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:48 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 15:18:55 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4), (b) (6) | 11 Mar 2021 12:43:01 |
| Query 'Data is required. Please complete.' answered with 'Unknown, not in medical records' (Site from System). | Marlee Smith (b) (4) (b) (4) | 09 Mar 2021 18:14:23 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 20 Jan 2021 15:49:15 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 19 Jan 2021 15:06:32 |
| User entered empty. | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:06:32 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:26:23

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:48 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered empty. | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:06:32 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:26:23

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:48 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered '12 Oct 2020' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:06:32 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:26:23

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:48 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered '0' | Marlee Smith (b) (4) | 19 Jan 2021 15:06:32 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:26:23

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:48 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'No (N)' | Marlee Smith (b) (4) | 19 Jan 2021 15:06:32 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:26:23

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:48 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered '21 Oct 2020' | Marlee Smith (b) (4) | 19 Jan 2021 15:06:32 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:26:23

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:48 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 22 Mar 2021 16:31:28 |
| User closed query 'Please confirm, as this does not seem to be a solicited event' (Site from CRA). | (b) (4), (b) (6) | 22 Mar 2021 16:31:26 |
| Query 'Please confirm, as this does not seem to be a solicited event' answered with 'updated' (Site from CRA). | Marlee Smith (b) (4) (b) (4) | 04 Mar 2021 15:59:25 |
| User entered 'No (N)' reason for change: Data Entry Error | Marlee Smith (b) (4) (b) (4) | 04 Mar 2021 15:59:17 |
| User opened query 'Please confirm, as this does not seem to be a solicited event' (Site from CRA). | (b) (4), (b) (6) | 03 Feb 2021 18:09:41 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 18:06:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'Yes (Y)' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:06:32 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:26:23

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:48 |
| User entered empty. | System | 19 Jan 2021 15:06:32 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:26:23

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:48 |
| User entered empty. | System | 19 Jan 2021 15:06:32 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:26:23

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:48 |
| User entered empty. | System | 19 Jan 2021 15:06:32 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:26:23

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:58 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| 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) (b) (4) | 19 Jan 2021 15:09:06 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 19 Jan 2021 15:09:06 |
| Data point term sent to Coder | System | 19 Jan 2021 15:08:00 |
| User entered 'Tylenol' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:07:43 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:26:23

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:58 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'No (N)' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:07:43 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:26:23

[Indication](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:58 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'pain related to acute incarcerated left hernia repair with mesh' | Marlee Smith (b) (4) | 19 Jan 2021 15:07:43 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:26:23

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:58 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered '500' | Marlee Smith (b) (4) | 19 Jan 2021 15:07:43 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:26:23

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:58 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'mg (mg)' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:07:43 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:26:23

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:58 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered empty. | Marlee Smith (b) (4) | 19 Jan 2021 15:07:43 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:26:23

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:58 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'as needed (PRN)' | Marlee Smith (b) (4) | 19 Jan 2021 15:07:43 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:26:23

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:58 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered empty. | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:07:43 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:26:23

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:58 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'Oral (ORAL)' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:07:43 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:26:23

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:58 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered empty. | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:07:43 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:26:23

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:58 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered '14 Oct 2020' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:07:43 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:26:23

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:58 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered '0' | Marlee Smith (b) (4) | 19 Jan 2021 15:07:43 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:26:23

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:58 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'No (N)' | Marlee Smith (b) (4) | 19 Jan 2021 15:07:43 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:26:23

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:58 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered '31 Oct 2020' | Marlee Smith (b) (4) | 19 Jan 2021 15:07:43 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:26:23

Was this medication taken for solicited event?

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:58 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 15:18:55 |
| User closed query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,). Please review and update as appropriate. Otherwise, provide clarification. ' (Site from DM). | (b) (4), (b) (6) | 05 Mar 2021 12:55:31 |
| Query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,). Please review and update as appropriate. Otherwise, provide clarification. ' answered with 'updated' (Site from DM). | Marlee Smith (b) (4) (b) (4) | 04 Mar 2021 15:59:44 |
| DataPoint Un-verified. | Marlee Smith (b) (4) (b) (4) | 04 Mar 2021 15:59:36 |
| User entered 'No (N)' reason for change: Data Entry Error | Marlee Smith (b) (4) (b) (4) | 04 Mar 2021 15:59:36 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:26:23

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| User opened query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,). Please review and update as appropriate. Otherwise, provide clarification. ' (Site from DM). | (b) (4), (b) (6) | 21 Feb 2021 10:10:19 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'Yes (Y)' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:07:43 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:26:23

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:58 |
| User entered empty. | System | 19 Jan 2021 15:07:43 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:26:23

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:58 |
| User entered empty. | System | 19 Jan 2021 15:07:43 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:26:23

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:58 |
| User entered empty. | System | 19 Jan 2021 15:07:43 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:26:23

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:59 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL - version WHODrug-Global-B3\202003. | Coder Import (b) (4) (b) (4) | 19 Jan 2021 15:12:06 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003. | Coder Import (b) (4) (b) (4) | 19 Jan 2021 15:12:06 |
| Data point term sent to Coder | System | 19 Jan 2021 15:09:02 |
| User entered 'tramadol' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:08:40 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:26:23

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:59 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'No (N)' | Marlee Smith (b) (4) | 19 Jan 2021 15:08:40 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:26:23

[Indication](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:59 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'pain related to acute incarcerated left hernia repair with mesh' | Marlee Smith (b) (4) | 19 Jan 2021 15:08:40 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:26:23

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:59 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered '50' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:08:40 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:26:23

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:59 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'mg (mg)' | Marlee Smith (b) (4) | 19 Jan 2021 15:08:40 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:26:23

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:59 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered empty. | Marlee Smith (b) (4) | 19 Jan 2021 15:08:40 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:26:23

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:59 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'once daily (QD)' | Marlee Smith (b) (4) | 19 Jan 2021 15:08:40 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:26:23

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:59 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered empty. | Marlee Smith (b) (4) | 19 Jan 2021 15:08:40 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:26:23

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:59 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'Oral (ORAL)' | Marlee Smith (b) (4) | 19 Jan 2021 15:08:40 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:26:23

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:59 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered empty. | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:08:40 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:26:23

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:59 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User closed query 'Per DM CLR: Con Med start date does not coincide with the timeframe of the AE indication upon checking in the AE eCRF (AE#3: 12Oct2020-21Oct2020). Please review and reconcile Con Med and AE start/stop dates as appropriate. Otherwise, clarify.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 14 Apr 2021 06:54:46 |
| Query 'Per DM CLR: Con Med start date does not coincide with the timeframe of the AE indication upon checking in the AE eCRF (AE#3: 12Oct2020-21Oct2020). Please review and reconcile Con Med and AE start/stop dates as appropriate. Otherwise, clarify.' answered with 'medical records state is was ordered on 21OCT and discontinued on 28OCT' (Site from DM). | Marlee Smith (b) (4) (b) (4) | 07 Apr 2021 15:51:46 |
| User opened query 'Per DM CLR: Con Med start date does not coincide with the timeframe of the AE indication upon checking in the AE eCRF (AE#3: 12Oct2020-21Oct2020). Please review and reconcile Con Med and AE start/stop dates as appropriate. Otherwise, clarify.' (Site from DM). | (b) (4), (b) (6) | 21 Feb 2021 10:11:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered '21 Oct 2020' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:08:40 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:26:23

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:59 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered '0' | Marlee Smith (b) (4) | 19 Jan 2021 15:08:40 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:26:23

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:59 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'No (N)' | Marlee Smith (b) (4) | 19 Jan 2021 15:08:40 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:26:23

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:59 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered '28 Oct 2020' | Marlee Smith (b) (4) | 19 Jan 2021 15:08:40 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:26:23

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:59 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 15:18:55 |
| User closed query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,). Please review and update as appropriate. Otherwise, provide clarification.' (Site from DM). | (b) (4), (b) (6) | 05 Mar 2021 12:55:24 |
| Query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,). Please review and update as appropriate. Otherwise, provide clarification.' answered with 'updated' (Site from DM). | Marlee Smith (b) (4) (b) (4) | 04 Mar 2021 16:00:25 |
| DataPoint Un-verified. | Marlee Smith (b) (4) (b) (4) | 04 Mar 2021 16:00:17 |
| User entered 'No (N)' reason for change: Data Entry Error | Marlee Smith (b) (4) (b) (4) | 04 Mar 2021 16:00:17 |
| User opened query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,). Please review and update as appropriate. Otherwise, provide clarification.' (Site from DM). | (b) (4), (b) (6) | 21 Feb 2021 10:11:42 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:26:23

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|------------------------|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'Yes (Y)' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:08:40 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:26:23

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:59 |
| User entered '1' | System | 19 Jan 2021 15:08:40 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:26:23

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:59 |
| User entered '1' | System | 19 Jan 2021 15:08:40 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:26:23

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:20:59 |
| User entered '804 (804)' | System | 19 Jan 2021 15:08:40 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:26:23

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:21:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: QUINOLONE ANTIBACTERIALS, ATC: FLUOROQUINOLONES, PRODUCT: LEVOFLOXACIN, PRODUCTSYNONYM: LOVENOX [LEVOFLOXACIN] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 20 Jan 2021 00:23:13 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 20 Jan 2021 00:23:13 |
| Data point term sent to Coder | System | 19 Jan 2021 15:10:03 |
| User entered 'lovenox' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:09:17 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:26:23

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:21:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'No (N)' | Marlee Smith (b) (4) | 19 Jan 2021 15:09:17 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:26:23

[Indication](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:21:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'left hernia repair with mesh' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:09:17 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:26:23

[Dose per administration](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:21:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 15:18:55 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4), (b) (6) | 11 Mar 2021 12:44:20 |
| Query 'Data is required. Please complete.' answered with 'Unknown, not in medical records' (Site from System). | Marlee Smith (b) (4) (b) (4) | 09 Mar 2021 18:14:54 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 20 Jan 2021 15:51:57 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 19 Jan 2021 15:09:17 |
| User entered empty. | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:09:17 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:26:23

[Dose unit](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:21:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 15:18:55 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4), (b) (6) | 11 Mar 2021 12:44:22 |
| Query 'Data is required. Please complete.' answered with 'Unknown, not in medical records' (Site from System). | Marlee Smith (b) (4) (b) (4) | 09 Mar 2021 18:14:58 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 20 Jan 2021 15:51:58 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 19 Jan 2021 15:09:17 |
| User entered empty. | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:09:17 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:26:23

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:21:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 15:18:55 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 20 Jan 2021 15:52:24 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered empty. | Marlee Smith (b) (4) | 19 Jan 2021 15:09:17 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:26:23

[Frequency](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:21:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 15:18:55 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4), (b) (6) | 11 Mar 2021 12:44:23 |
| Query 'Data is required. Please complete.' answered with 'Unknown, not in medical records' (Site from System). | Marlee Smith (b) (4) (b) (4) | 09 Mar 2021 18:15:03 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 20 Jan 2021 15:52:37 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 19 Jan 2021 15:09:17 |
| User entered empty. | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:09:17 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:26:23

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:21:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 15:18:55 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 20 Jan 2021 15:52:28 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered empty. | Marlee Smith (b) (4) | 19 Jan 2021 15:09:17 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:26:23

[Route of administration](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:21:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 15:18:55 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4), (b) (6) | 11 Mar 2021 12:44:35 |
| Query 'Data is required. Please complete.' answered with 'Unknown, not in medical records' (Site from System). | Marlee Smith (b) (4) (b) (4) | 09 Mar 2021 18:15:08 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 20 Jan 2021 15:52:33 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 19 Jan 2021 15:09:17 |
| User entered empty. | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:09:17 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:26:23

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:21:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered empty. | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:09:17 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:26:23

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:21:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User closed query 'Per DM CLR: Con Med start date does not coincide with the timeframe of the AE indication upon checking in the AE eCRF (AE#3: 12Oct2020-21Oct2020). Please review and reconcile Con Med and AE start/stop dates as appropriate. Otherwise, clarify.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 14 Apr 2021 06:54:53 |
| Query 'Per DM CLR: Con Med start date does not coincide with the timeframe of the AE indication upon checking in the AE eCRF (AE#3: 12Oct2020-21Oct2020). Please review and reconcile Con Med and AE start/stop dates as appropriate. Otherwise, clarify.' answered with 'medical records state it was ordered on 21OCT and discontinued on 28OCT' (Site from DM). | Marlee Smith (b) (4) (b) (4) | 07 Apr 2021 15:52:35 |
| User opened query 'Per DM CLR: Con Med start date does not coincide with the timeframe of the AE indication upon checking in the AE eCRF (AE#3: 12Oct2020-21Oct2020). Please review and reconcile Con Med and AE start/stop dates as appropriate. Otherwise, clarify.' (Site from DM). | (b) (4), (b) (6) | 21 Feb 2021 10:12:32 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered '21 Oct 2020' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:09:17 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:26:23

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:21:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered '0' | Marlee Smith (b) (4) | 19 Jan 2021 15:09:17 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:26:23

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:21:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'No (N)' | Marlee Smith (b) (4) | 19 Jan 2021 15:09:17 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:26:23

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:21:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered '28 Oct 2020' | Marlee Smith (b) (4) | 19 Jan 2021 15:09:17 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:26:23

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:21:01 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 15:18:55 |
| User closed query 'Per DM CLR: Con Med start date does not coincide with the timeframe of the AE indication upon checking in the AE eCRF (AE#3: 12Oct2020-21Oct2020). Please review and reconcile Con Med and AE start/stop dates as appropriate. Otherwise, clarify.' (Site from DM). | (b) (4), (b) (6) | 05 Mar 2021 12:57:01 |
| Query 'Per DM CLR: Con Med start date does not coincide with the timeframe of the AE indication upon checking in the AE eCRF (AE#3: 12Oct2020-21Oct2020). Please review and reconcile Con Med and AE start/stop dates as appropriate. Otherwise, clarify.' answered with 'updated' (Site from DM). | Marlee Smith (b) (4) (b) (4) | 04 Mar 2021 16:00:52 |
| DataPoint Un-verified. | Marlee Smith (b) (4) (b) (4) | 04 Mar 2021 16:00:41 |
| User entered 'No (N)' reason for change: Data Entry Error | Marlee Smith (b) (4) (b) (4) | 04 Mar 2021 16:00:41 |
| User opened query 'Per DM CLR: Con Med start date does not coincide with the timeframe of the AE indication upon checking in the AE eCRF (AE#3: 12Oct2020-21Oct2020). Please review and reconcile Con Med and AE start/stop dates as appropriate. Otherwise, clarify.' (Site from DM). | (b) (4), (b) (6) | 21 Feb 2021 10:12:45 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'Yes (Y)' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:09:17 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:26:23

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:21:01 |
| User entered empty. | System | 19 Jan 2021 15:09:17 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:26:23

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:21:01 |
| User entered empty. | System | 19 Jan 2021 15:09:17 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:26:23

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:21:01 |
| User entered empty. | System | 19 Jan 2021 15:09:17 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:26:23

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:21:05 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE, PRODUCTSYNONYM: ROCEPHIN [CEFTRIAXONE] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 19 Jan 2021 15:11:08 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 19 Jan 2021 15:11:08 |
| Data point term sent to Coder | System | 19 Jan 2021 15:10:06 |
| User entered 'rocephin' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:09:57 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:26:23

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:21:05 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'No (N)' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:09:57 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:26:23

[Indication](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:21:05 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'urinary tract infection' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:09:57 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:26:23

[Dose per administration](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:21:05 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 15:18:55 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4), (b) (6) | 11 Mar 2021 12:44:48 |
| Query 'Data is required. Please complete.' answered with 'Unknown, not in medical records' (Site from System). | Marlee Smith (b) (4) (b) (4) | 09 Mar 2021 18:15:27 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 20 Jan 2021 15:53:07 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 19 Jan 2021 15:09:57 |
| User entered empty. | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:09:57 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:26:23

[Dose unit](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:21:05 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 15:18:55 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4), (b) (6) | 11 Mar 2021 12:44:50 |
| Query 'Data is required. Please complete.' answered with 'Unknown, not in medical records' (Site from System). | Marlee Smith (b) (4) (b) (4) | 09 Mar 2021 18:15:31 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 20 Jan 2021 15:53:04 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 19 Jan 2021 15:09:57 |
| User entered empty. | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:09:57 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:26:23

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:21:05 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 15:18:55 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 20 Jan 2021 15:53:11 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered empty. | Marlee Smith (b) (4) | 19 Jan 2021 15:09:57 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:26:23

[Frequency](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:21:05 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 15:18:55 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4), (b) (6) | 11 Mar 2021 12:44:53 |
| Query 'Data is required. Please complete.' answered with 'Unknown, not in medical records' (Site from System). | Marlee Smith (b) (4) (b) (4) | 09 Mar 2021 18:15:35 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 20 Jan 2021 16:02:02 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 19 Jan 2021 15:09:57 |
| User entered empty. | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:09:57 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:26:23

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:21:05 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 15:18:55 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 20 Jan 2021 16:01:58 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered empty. | Marlee Smith (b) (4) | 19 Jan 2021 15:09:57 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:26:23

[Route of administration](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:21:05 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 15:18:55 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4), (b) (6) | 11 Mar 2021 12:44:55 |
| Query 'Data is required. Please complete.' answered with 'Unknown, not in medical records' (Site from System). | Marlee Smith (b) (4) (b) (4) | 09 Mar 2021 18:15:40 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 20 Jan 2021 16:01:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 19 Jan 2021 15:09:57 |
| User entered empty. | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:09:57 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:26:23

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:21:05 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 15:18:55 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 20 Jan 2021 16:01:54 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered empty. | Marlee Smith (b) (4) | 19 Jan 2021 15:09:57 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:26:23

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:21:05 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered '26 Oct 2020' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:09:57 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:26:23

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:21:05 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered '0' | Marlee Smith (b) (4) | 19 Jan 2021 15:09:57 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:26:23

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:21:05 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'No (N)' | Marlee Smith (b) (4) | 19 Jan 2021 15:09:57 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:26:23

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:21:05 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered '28 Oct 2020' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:09:57 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:26:23

Was this medication taken for solicited event?

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:21:05 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 15:18:55 |
| User closed query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,). Please review and update as appropriate. Otherwise, provide clarification. ' (Site from DM). | (b) (4), (b) (6) | 05 Mar 2021 12:57:09 |
| Query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,). Please review and update as appropriate. Otherwise, provide clarification. ' answered with 'updated' (Site from DM). | Marlee Smith (b) (4) (b) (4) | 04 Mar 2021 16:01:18 |
| DataPoint Un-verified. | Marlee Smith (b) (4) (b) (4) | 04 Mar 2021 16:01:10 |
| User entered 'No (N)' reason for change: Data Entry Error | Marlee Smith (b) (4) (b) (4) | 04 Mar 2021 16:01:10 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:26:23

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| User opened query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,). Please review and update as appropriate. Otherwise, provide clarification. ' (Site from DM). | (b) (4), (b) (6) | 21 Feb 2021 10:13:04 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'Yes (Y)' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:09:57 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:26:23

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:21:05 |
| User entered empty. | System | 19 Jan 2021 15:09:57 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:26:23

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:21:05 |
| User entered empty. | System | 19 Jan 2021 15:09:57 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:26:23

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:21:05 |
| User entered empty. | System | 19 Jan 2021 15:09:57 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:26:23

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:21:07 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| 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) (b) (4) | 19 Jan 2021 15:12:07 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 19 Jan 2021 15:12:07 |
| Data point term sent to Coder | System | 19 Jan 2021 15:11:06 |
| User entered 'zofran' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:10:29 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:26:23

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:21:07 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'No (N)' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:10:29 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:26:23

[Indication](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:21:07 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'urinary tract infection' | Marlee Smith (b) (4) | 19 Jan 2021 15:10:29 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:26:23

[Dose per administration](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:21:07 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 15:18:55 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4), (b) (6) | 11 Mar 2021 12:45:01 |
| Query 'Data is required. Please complete.' answered with 'Unknown, not in medical records' (Site from System). | Marlee Smith (b) (4) (b) (4) | 09 Mar 2021 18:15:56 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 20 Jan 2021 16:02:48 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 19 Jan 2021 15:10:29 |
| User entered empty. | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:10:29 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:26:23

[Dose unit](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:21:07 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 15:18:55 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4), (b) (6) | 11 Mar 2021 12:45:03 |
| Query 'Data is required. Please complete.' answered with 'Unknown, not in medical records' (Site from System). | Marlee Smith (b) (4) (b) (4) | 09 Mar 2021 18:15:59 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 20 Jan 2021 16:02:49 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 19 Jan 2021 15:10:29 |
| User entered empty. | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:10:29 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:26:23

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:21:07 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 15:18:55 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 20 Jan 2021 16:02:52 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered empty. | Marlee Smith (b) (4) | 19 Jan 2021 15:10:29 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:26:23

[Frequency](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:21:07 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 15:18:55 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4), (b) (6) | 11 Mar 2021 12:45:06 |
| Query 'Data is required. Please complete.' answered with 'Unknown, not in medical records' (Site from System). | Marlee Smith (b) (4) (b) (4) | 09 Mar 2021 18:16:03 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 20 Jan 2021 16:02:57 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 19 Jan 2021 15:10:29 |
| User entered empty. | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:10:29 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:26:23

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:21:07 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 15:18:55 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 20 Jan 2021 16:02:58 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered empty. | Marlee Smith (b) (4) | 19 Jan 2021 15:10:29 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:26:23

[Route of administration](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:21:07 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 15:18:55 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4), (b) (6) | 11 Mar 2021 12:45:09 |
| Query 'Data is required. Please complete.' answered with 'Unknown, not in medical records' (Site from System). | Marlee Smith (b) (4) (b) (4) | 09 Mar 2021 18:16:06 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 20 Jan 2021 16:03:00 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 19 Jan 2021 15:10:29 |
| User entered empty. | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:10:29 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:26:23

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:21:07 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 15:18:55 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 20 Jan 2021 16:03:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered empty. | Marlee Smith (b) (4) | 19 Jan 2021 15:10:29 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:26:23

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:21:07 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered '26 Oct 2020' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:10:29 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:26:23

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:21:07 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered '0' | Marlee Smith (b) (4) | 19 Jan 2021 15:10:29 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:26:23

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:21:07 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'No (N)' | Marlee Smith (b) (4) | 19 Jan 2021 15:10:29 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:26:23

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:21:07 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered '28 Oct 2020' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:10:29 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:26:23

Was this medication taken for solicited event?

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:21:07 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 15:18:55 |
| User closed query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,). Please review and update as appropriate. Otherwise, provide clarification. ' (Site from DM). | (b) (4), (b) (6) | 05 Mar 2021 12:58:01 |
| Query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,). Please review and update as appropriate. Otherwise, provide clarification. ' answered with 'updated' (Site from DM). | Marlee Smith (b) (4) (b) (4) | 04 Mar 2021 16:01:51 |
| DataPoint Un-verified. | Marlee Smith (b) (4) (b) (4) | 04 Mar 2021 16:01:43 |
| User entered 'No (N)' reason for change: Data Entry Error | Marlee Smith (b) (4) (b) (4) | 04 Mar 2021 16:01:43 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:26:23

Was this medication taken for solicited event?

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| User opened query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,). Please review and update as appropriate. Otherwise, provide clarification. ' (Site from DM). | (b) (4), (b) (6) | 21 Feb 2021 10:13:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'Yes (Y)' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:10:29 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:26:23

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:21:07 |
| User entered empty. | System | 19 Jan 2021 15:10:29 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:26:23

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:21:07 |
| User entered empty. | System | 19 Jan 2021 15:10:29 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:26:23

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:21:07 |
| User entered empty. | System | 19 Jan 2021 15:10:29 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:26:23

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN ASPART, PRODUCTSYNONYM: NOVOLOG - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 19 Jan 2021 15:13:08 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 19 Jan 2021 15:13:08 |
| Data point term sent to Coder | System | 19 Jan 2021 15:12:07 |
| User entered 'NovoLog flexpen' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:11:28 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:26:23

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'No (N)' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:11:28 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:26:23

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'diabetes 2' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:11:28 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:26:23

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered '100' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:11:28 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:26:23

[Dose unit](#)

| Audit | User | Time (GMT) |
|------------------------------|---------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'Other (OTHER)' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:11:28 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:26:23

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'unit/mL' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:11:28 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:26:23

[Frequency](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'three times daily (TID)' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:11:28 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:26:23

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered empty. | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:11:28 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:26:23

[Route of administration](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'Subcutaneous (SUBCUTANEOUS)' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:11:28 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:26:23

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered empty. | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:11:28 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered '03 Mar 2016' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:11:28 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:26:23

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered '0' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:11:28 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:26:23

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'Yes (Y)' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:11:28 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:26:23

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered empty. | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:11:28 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:26:23

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'No (N)' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:11:28 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:26:23

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '3' | System | 19 Jan 2021 15:11:28 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:26:23

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 19 Jan 2021 15:11:28 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:26:23

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 19 Jan 2021 15:11:28 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:26:23

Name of Medication

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User closed query 'Please update to Ventolin HFA, per source.' (Site from CRA). | (b) (4) | 12 Apr 2021 19:18:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 12 Apr 2021 19:18:15 |
| User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL SULFATE, PRODUCTSYNONYM: VENTOLIN HFA - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 08 Apr 2021 15:36:49 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 08 Apr 2021 15:36:49 |
| Data point term sent to Coder | System | 08 Apr 2021 15:36:20 |
| Query 'Please update to Ventolin HFA, per source.' answered with 'updated' (Site from CRA). | Marlee Smith (b) (4) | 08 Apr 2021 15:36:13 |
| DataPoint Un-verified. | (b) (4) | |
| | Marlee Smith (b) (4) | 08 Apr 2021 15:35:50 |
| Coding entries removed. | (b) (4) | |
| | Marlee Smith (b) (4) | 08 Apr 2021 15:35:50 |
| User entered 'VENTOLIN HFA' reason for change: Data Entry Error | Marlee Smith (b) (4) | 08 Apr 2021 15:35:50 |
| User opened query 'Please update to Ventolin HFA, per source.' (Site from CRA). | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 15:27:04 |
| | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: VENTOLIN [SALBUTAMOL] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 19 Jan 2021 15:14:07 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 19 Jan 2021 15:14:07 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:26:23

[Name of Medication](#)

| Audit | User | Time (GMT) |
|-------------------------------|----------------------|----------------------|
| Data point term sent to Coder | System | 19 Jan 2021 15:13:09 |
| User entered 'ventolin' | Marlee Smith (b) (4) | 19 Jan 2021 15:12:12 |
| | (b) (4) | |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:26:23

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'No (N)' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:12:12 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:26:23

[Indication](#)

| Audit | User | Time (GMT) |
|------------------------------------|---------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'shortness of breath' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:12:12 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:26:23

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered '90' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:12:12 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:26:23

[Dose unit](#)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| | (b) (4) | |
| Query 'per source, dose unit is mcg' canceled (Site from CRA). | (b) (4), (b) (6) | 08 Apr 2021 15:32:48 |
| | | |
| User opened query 'per source, dose unit is mcg' (Site from CRA). | (b) (4), (b) (6) | 08 Apr 2021 15:30:40 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| | | |
| User entered 'ug (ug)' | Marlee Smith (b) (4) | 19 Jan 2021 15:12:12 |
| | (b) (4) | |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:26:23

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered empty. | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:12:12 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:26:23

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|---------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'as needed (PRN)' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:12:12 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:26:23

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered empty. | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:12:12 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:26:23

[Route of administration](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:12:12 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:26:23

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered empty. | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:12:12 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:26:23

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition (UNK 2017). Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify. ' (Site from DM). | (b) (4) (b) (4), (b) (6) | 11 Mar 2021 16:24:20 |
| Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition (UNK 2017). Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify. ' answered with 'updated' (Site from DM). | Marlee Smith (b) (4) (b) (4) | 09 Mar 2021 15:20:21 |
| User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition (UNK 2017). Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify. ' (Site from DM). | (b) (4), (b) (6) | 21 Feb 2021 10:14:23 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered '03 Mar 2016' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:12:12 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:26:23

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered '0' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:12:12 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:26:23

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'Yes (Y)' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:12:12 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:26:23

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered empty. | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:12:12 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:26:23

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'No (N)' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:12:12 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:26:23

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 19 Jan 2021 15:12:12 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:26:23

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 19 Jan 2021 15:12:12 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:26:23

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 19 Jan 2021 15:12:12 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:26:23

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS, ATC: GLUCOCORTICOIDS, PRODUCT: FLUTICASONE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 19 Jan 2021 15:14:07 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 19 Jan 2021 15:14:07 |
| Data point term sent to Coder | System | 19 Jan 2021 15:13:10 |
| User entered 'fluticasone' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:12:54 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:26:23

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'No (N)' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:12:54 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:26:23

[Indication](#)

| Audit | User | Time (GMT) |
|-----------------------------------|---------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'seasonal allergies' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:12:54 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:26:23

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered '50' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:12:54 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:26:23

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'ug (ug)' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:12:54 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:26:23

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered empty. | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:12:54 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:26:23

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|---------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'once daily (QD)' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:12:54 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:26:23

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered empty. | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:12:54 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:26:23

[Route of administration](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:12:54 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:26:23

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered empty. | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:12:54 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:26:23

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition (UNK 2018). Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify. ' (Site from DM). | (b) (4) (b) (4), (b) (6) | 11 Mar 2021 16:24:33 |
| Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition (UNK 2018). Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify. ' answered with 'updated' (Site from DM). | Marlee Smith (b) (4) (b) (4) | 09 Mar 2021 20:03:08 |
| User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition (UNK 2018). Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify. ' (Site from DM). | (b) (4), (b) (6) | 21 Feb 2021 10:18:24 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered '28 Oct 2016' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:12:54 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:26:23

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered '0' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:12:54 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:26:23

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'Yes (Y)' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:12:54 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:26:23

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered empty. | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:12:54 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:26:23

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'No (N)' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:12:54 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:26:23

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 19 Jan 2021 15:12:54 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:26:23

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 19 Jan 2021 15:12:54 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:26:23

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 19 Jan 2021 15:12:54 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:26:23

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 19 Jan 2021 15:15:06 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 19 Jan 2021 15:15:06 |
| Data point term sent to Coder | System | 19 Jan 2021 15:14:12 |
| User entered 'vitamin D3' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:13:32 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:26:23

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'Yes (Y)' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:13:32 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:26:23

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'supplement' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:13:32 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:26:23

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered '10000' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:13:32 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:26:23

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'IU (IU)' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:13:32 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:26:23

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered empty. | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:13:32 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:26:23

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|---------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'once daily (QD)' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:13:32 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:26:23

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered empty. | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:13:32 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:26:23

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'Oral (ORAL)' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:13:32 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:26:23

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered empty. | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:13:32 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered '13 Oct 2020' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:13:32 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:26:23

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered '0' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:13:32 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:26:23

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'Yes (Y)' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:13:32 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:26:23

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered empty. | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:13:32 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:26:23

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'No (N)' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:13:32 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:26:23

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 19 Jan 2021 15:13:32 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:26:23

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 19 Jan 2021 15:13:32 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:26:23

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 19 Jan 2021 15:13:32 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:26:23

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: ZINC, PRODUCT: ZINC - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 19 Jan 2021 15:16:07 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 19 Jan 2021 15:16:07 |
| Data point term sent to Coder | System | 19 Jan 2021 15:15:15 |
| User entered 'zinc' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:14:22 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:26:23

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'Yes (Y)' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:14:22 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:26:23

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'supplement' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:14:22 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:26:23

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'I' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:14:22 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:26:23

[Dose unit](#)

| Audit | User | Time (GMT) |
|--------------------------------|---------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'tablet (TABLET)' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:14:22 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:26:23

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered empty. | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:14:22 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:26:23

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|---------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'once daily (QD)' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:14:22 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:26:23

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered empty. | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:14:22 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:26:23

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'Oral (ORAL)' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:14:22 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:26:23

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 20 Jan 2021 16:10:02 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 20 Jan 2021 16:10:00 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered empty. | Marlee Smith (b) (4) | 19 Jan 2021 15:14:22 |
| | (b) (4) | |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered '13 Oct 2020' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:14:22 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:26:23

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered '0' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:14:22 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:26:23

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'Yes (Y)' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:14:22 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:26:23

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered empty. | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:14:22 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:26:23

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'No (N)' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:14:22 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:26:23

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 19 Jan 2021 15:14:22 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:26:23

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 19 Jan 2021 15:14:22 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:26:23

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 19 Jan 2021 15:14:22 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:26:23

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:21:18 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: TESTOSTERONE-5-ALPHA REDUCTASE INHIBITORS, PRODUCT: FINASTERIDE, PRODUCTSYNONYM: PROSCAR - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 20 Jan 2021 08:25:01 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 20 Jan 2021 08:25:01 |
| Data point term sent to Coder | System | 19 Jan 2021 15:15:15 |
| User entered 'proscar' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:15:03 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:26:23

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:21:18 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'No (N)' | Marlee Smith (b) (4) | 19 Jan 2021 15:15:03 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:26:23

[Indication](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:21:18 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'acute urinary retention requiring foley catheter' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:15:03 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:26:23

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:21:18 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered '5' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:15:03 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:26:23

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:21:18 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'mg (mg)' | Marlee Smith (b) (4) | 19 Jan 2021 15:15:03 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:26:23

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:21:18 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered empty. | Marlee Smith (b) (4) | 19 Jan 2021 15:15:03 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:26:23

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:21:18 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'once daily (QD)' | Marlee Smith (b) (4) | 19 Jan 2021 15:15:03 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:26:23

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:21:18 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered empty. | Marlee Smith (b) (4) | 19 Jan 2021 15:15:03 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:26:23

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:21:18 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'Oral (ORAL)' | Marlee Smith (b) (4) | 19 Jan 2021 15:15:03 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:26:23

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:21:18 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered empty. | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:15:03 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:26:23

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:21:18 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered '21 Oct 2020' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:15:03 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:26:23

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:21:18 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered '0' | Marlee Smith (b) (4) | 19 Jan 2021 15:15:03 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:26:23

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:21:18 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 15:18:55 |
| 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) | 25 Mar 2021 08:49:09 |
| Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'updated' (Site from DM). | Marlee Smith (b) (4) (b) (4) | 23 Mar 2021 17:13:01 |
| DataPoint Un-verified. | Marlee Smith (b) (4) (b) (4) | 23 Mar 2021 17:12:44 |
| User entered 'No (N)' reason for change: Data Entry Error | Marlee Smith (b) (4) (b) (4) | 23 Mar 2021 17:12:44 |
| 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) | 21 Feb 2021 10:19:23 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'Yes (Y)' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:15:03 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:26:23

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:21:18 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 15:18:55 |
| DataPoint Un-verified. | Marlee Smith (b) (4) | 23 Mar 2021 17:12:44 |
| User entered '21 Oct 2020' reason for change: Data Entry Error | (b) (4) Marlee Smith (b) (4) | 23 Mar 2021 17:12:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered empty. | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:15:03 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:26:23

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:21:18 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 15:18:55 |
| User closed query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,). Please review and update as appropriate. Otherwise, provide clarification.' (Site from DM). | (b) (4), (b) (6) | 05 Mar 2021 12:58:27 |
| Query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,). Please review and update as appropriate. Otherwise, provide clarification.' answered with 'updated' (Site from DM). | Marlee Smith (b) (4) (b) (4) | 04 Mar 2021 15:56:57 |
| DataPoint Un-verified. | Marlee Smith (b) (4) (b) (4) | 04 Mar 2021 15:56:50 |
| User entered 'No (N)' reason for change: Data Entry Error | Marlee Smith (b) (4) (b) (4) | 04 Mar 2021 15:56:50 |
| User opened query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,). Please review and update as appropriate. Otherwise, provide clarification.' (Site from DM). | (b) (4), (b) (6) | 21 Feb 2021 10:19:43 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:26:23

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|------------------------|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:46:08 |
| User entered 'Yes (Y)' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:15:03 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:26:23

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:21:18 |
| User entered '1' | System | 19 Jan 2021 15:15:03 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:26:23

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:21:18 |
| User entered '1' | System | 19 Jan 2021 15:15:03 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:26:23

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:21:18 |
| User entered '804 (804)' | System | 19 Jan 2021 15:15:03 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:26:23

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:21:19 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 15:18:55 |
| User coded data point as ATC: VARIOUS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: MEDICAL GASES, PRODUCT: OXYGEN - version WHODrug-Global-B3\202003. | Coder Import (b) (4) (b) (4) | 19 Mar 2021 09:45:46 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003. | Coder Import (b) (4) (b) (4) | 19 Mar 2021 09:45:46 |
| Data point term sent to Coder | System | 09 Mar 2021 15:24:46 |
| User entered 'oxygen' | Marlee Smith (b) (4) (b) (4) | 09 Mar 2021 15:24:34 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:26:23

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:21:19 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 15:18:55 |
| User entered 'No (N)' | Marlee Smith (b) (4) | 09 Mar 2021 15:24:34 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:26:23

[Indication](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:21:19 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 15:18:55 |
| User entered 'acute hypoxemic respiratory failure' | Marlee Smith (b) (4) | 09 Mar 2021 15:24:34 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:26:23

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:21:19 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 15:18:55 |
| User entered 'unk' | Marlee Smith (b) (4) | 09 Mar 2021 15:24:34 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:26:23

[Dose unit](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:21:19 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 15:18:55 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4), (b) (6) | 11 Mar 2021 12:48:20 |
| Query 'Data is required. Please complete.' answered with 'Unknown, not in medical records' (Site from System). | Marlee Smith (b) (4) (b) (4) | 09 Mar 2021 18:16:53 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 09 Mar 2021 15:24:34 |
| User entered empty. | Marlee Smith (b) (4) (b) (4) | 09 Mar 2021 15:24:34 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:26:23

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:21:19 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 15:18:55 |
| User entered empty. | Marlee Smith (b) (4) | 09 Mar 2021 15:24:34 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:26:23

[Frequency](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:21:19 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 15:18:55 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4), (b) (6) | 11 Mar 2021 12:48:22 |
| Query 'Data is required. Please complete.' answered with 'Unknown, not in medical records' (Site from System). | Marlee Smith (b) (4) (b) (4) | 09 Mar 2021 18:16:58 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 09 Mar 2021 15:24:34 |
| User entered empty. | Marlee Smith (b) (4) (b) (4) | 09 Mar 2021 15:24:34 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:26:23

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:21:19 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 15:18:55 |
| User entered empty. | Marlee Smith (b) (4) (b) (4) | 09 Mar 2021 15:24:34 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:26:23

[Route of administration](#)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:21:19 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 15:18:55 |
| User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))' | Marlee Smith (b) (4) | 09 Mar 2021 15:24:34 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:26:23

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:21:19 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 15:18:55 |
| User entered empty. | Marlee Smith (b) (4) (b) (4) | 09 Mar 2021 15:24:34 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:26:23

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:21:19 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 15:18:55 |
| User entered '26 Oct 2020' | Marlee Smith (b) (4) | 09 Mar 2021 15:24:34 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:26:23

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:21:19 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 15:18:55 |
| User entered '0' | Marlee Smith (b) (4) | 09 Mar 2021 15:24:34 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:26:23

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:21:19 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 15:18:55 |
| User entered 'No (N)' | Marlee Smith (b) (4) (b) (4) | 09 Mar 2021 15:24:34 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:26:23

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:21:19 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 15:18:55 |
| User entered '28 Oct 2020' | Marlee Smith (b) (4) | 09 Mar 2021 15:24:34 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:26:23

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:21:19 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 15:18:55 |
| User entered 'No (N)' | Marlee Smith (b) (4) | 09 Mar 2021 15:24:34 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:26:23

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:21:19 |
| User entered empty. | System | 09 Mar 2021 15:24:34 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:26:23

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:21:19 |
| User entered empty. | System | 09 Mar 2021 15:24:34 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:26:23

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 17:21:19 |
| User entered empty. | System | 09 Mar 2021 15:24:34 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:26:23

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 12 Apr 2021 19:19:20 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: CLONAZEPAM, PRODUCTSYNONYM: KLONOPIN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 08 Apr 2021 15:52:55 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 08 Apr 2021 15:52:55 |
| | (b) (4) | |
| Data point term sent to Coder | System | 08 Apr 2021 15:51:55 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: CLONAZEPAM, PRODUCTSYNONYM: KLONOPIN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 08 Apr 2021 15:51:42 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 08 Apr 2021 15:51:42 |
| | (b) (4) | |
| Data point term sent to Coder | System | 08 Apr 2021 15:50:52 |
| Data point term sent to Coder | System | 08 Apr 2021 15:47:39 |
| User entered 'KlonoPIN' | Marlee Smith (b) (4) | 08 Apr 2021 15:47:04 |
| | (b) (4) | |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:26:23

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 19:19:20 |
| User entered 'No (N)' | Marlee Smith (b) (4) (b) (4) | 08 Apr 2021 15:47:04 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:26:23

[Indication](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 19:19:20 |
| User entered 'Anxiety' reason for change: Data Entry Error | Marlee Smith (b) (4) (b) (4) | 08 Apr 2021 15:51:30 |
| User entered 'unknown' reason for change: Data Entry Error | Marlee Smith (b) (4) (b) (4) | 08 Apr 2021 15:51:08 |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 08 Apr 2021 15:50:49 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 08 Apr 2021 15:50:49 |
| User entered 'anxiety' reason for change: Data Entry Error | Marlee Smith (b) (4) (b) (4) | 08 Apr 2021 15:50:49 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 08 Apr 2021 15:47:04 |
| User entered empty. | Marlee Smith (b) (4) (b) (4) | 08 Apr 2021 15:47:04 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:26:23

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 19:19:20 |
| User entered 'I' | Marlee Smith (b) (4) (b) (4) | 08 Apr 2021 15:47:04 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:26:23

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 19:19:20 |
| User entered 'mg (mg)' | Marlee Smith (b) (4) (b) (4) | 08 Apr 2021 15:47:04 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:26:23

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 19:19:20 |
| User entered empty. | Marlee Smith (b) (4) (b) (4) | 08 Apr 2021 15:47:04 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:26:23

[Frequency](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User closed query 'Per CDM: "Frequency" is recorded as "other - once at night". Please review and confirm if "once daily" appropriate. If not, please clarify. ' (Site from DM). | (b) (4) (b) (4), (b) (6) | 13 Apr 2021 15:15:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 12 Apr 2021 19:19:20 |
| Query 'Per CDM: "Frequency" is recorded as "other - once at night". Please review and confirm if "once daily" appropriate. If not, please clarify. ' answered with 'updated' (Site from DM). | Marlee Smith (b) (4) (b) (4) | 12 Apr 2021 13:33:40 |
| User entered 'once daily (QD)' reason for change: Data Entry Error | Marlee Smith (b) (4) (b) (4) | 12 Apr 2021 13:33:23 |
| User opened query 'Per CDM: "Frequency" is recorded as "other - once at night". Please review and confirm if "once daily" appropriate. If not, please clarify. ' (Site from DM). | (b) (4), (b) (6) | 12 Apr 2021 03:47:54 |
| User entered 'other (OTHER)' | Marlee Smith (b) (4) (b) (4) | 08 Apr 2021 15:47:04 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:26:23

If frequency is Other, specify

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 19:19:20 |
| User entered empty; reason for change Data Entry Error | Marlee Smith (b) (4) (b) (4) | 12 Apr 2021 13:33:23 |
| User entered 'once at night' | Marlee Smith (b) (4) (b) (4) | 08 Apr 2021 15:47:04 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:26:23

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 19:19:20 |
| User entered 'Oral (ORAL)' | Marlee Smith (b) (4) (b) (4) | 08 Apr 2021 15:47:04 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:26:23

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 19:19:20 |
| User entered empty. | Marlee Smith (b) (4) (b) (4) | 08 Apr 2021 15:47:04 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:26:23

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

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 19:19:20 |
| User entered '17 Mar 2020' | Marlee Smith (b) (4) (b) (4) | 08 Apr 2021 15:47:04 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:26:23

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 19:19:20 |
| User entered '0' | Marlee Smith (b) (4) (b) (4) | 08 Apr 2021 15:47:04 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:26:23

[Ongoing?](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 19:19:20 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Marlee Smith (b) (4) (b) (4) | 08 Apr 2021 15:50:08 |
| User entered 'No (N)' | Marlee Smith (b) (4) (b) (4) | 08 Apr 2021 15:47:04 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:26:23

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 19:19:20 |
| User entered empty; reason for change Data Entry Error | Marlee Smith (b) (4) (b) (4) | 08 Apr 2021 15:50:08 |
| User closed query 'Data entered is non-conformant. Please correct.' (Site from System). | System | 08 Apr 2021 15:47:21 |
| User entered 'un UNK 2021' reason for change: Data Entry Error | Marlee Smith (b) (4) (b) (4) | 08 Apr 2021 15:47:21 |
| User opened query 'Data entered is non-conformant. Please correct.' (Site from System). | System | 08 Apr 2021 15:47:04 |
| User entered ' 2021' (non-conformant). | Marlee Smith (b) (4) (b) (4) | 08 Apr 2021 15:47:04 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:26:23

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 19:19:20 |
| User entered 'No (N)' | Marlee Smith (b) (4) (b) (4) | 08 Apr 2021 15:47:04 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:26:23

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '1' | System | 12 Apr 2021 13:33:23 |
| User entered empty. | System | 08 Apr 2021 15:47:04 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:26:23

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '1' | System | 12 Apr 2021 13:33:23 |
| User entered empty. | System | 08 Apr 2021 15:47:04 |

US3722338

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:26:23

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 12 Apr 2021 13:33:23 |
| User entered empty. | System | 08 Apr 2021 15:47:04 |

US3722338

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:26:23

[Were any concomitant procedures performed?](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 10:26:35 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:21:41 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 18:34:49 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Jan 2021 18:41:24 |
| User closed query 'Per ETRTR: Please confirm no Procedure was done for SAE "Hernia Repair". Update ConProcedures and AE CRF otherwise, thanks.' (Site from CRA). | (b) (4), (b) (6) | 14 Jan 2021 18:41:20 |
| Query 'Per ETRTR: Please confirm no Procedure was done for SAE "Hernia Repair". Update ConProcedures and AE CRF otherwise, thanks.' answered with 'updated' (Site from CRA). | Marlee Smith (b) (4) (b) (4) | 10 Nov 2020 18:51:41 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Marlee Smith (b) (4) (b) (4) | 10 Nov 2020 18:51:36 |
| User opened query 'Per ETRTR: Please confirm no Procedure was done for SAE "Hernia Repair". Update ConProcedures and AE CRF otherwise, thanks.' (Site from CRA). | (b) (4), (b) (6) | 27 Oct 2020 22:48:31 |
| User entered 'No (N)' | Kayla Peay (b) (4) (b) (4) | 20 Aug 2020 17:40:42 |

US3722338

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:26:23

Procedure/Surgery date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 03 Feb 2021 17:09:15 |
| User closed query 'Please verify procedure date, as source indicates 12Oct20. Source may need to be updated. ' (Site from CRA). | (b) (4), (b) (6) | 03 Feb 2021 17:09:14 |
| Query 'Please verify procedure date, as source indicates 12Oct20. Source may need to be updated. ' answered with 'Date has been updated to correct date' (Site from CRA). | Sara Poff (b) (4) | 02 Feb 2021 02:01:08 |
| | (b) (4) | |
| User entered '12 Oct 2020' reason for change: Data Entry Error | Sara Poff (b) (4) | 02 Feb 2021 02:00:52 |
| | (b) (4) | |
| User opened query 'Please verify procedure date, as source indicates 12Oct20. Source may need to be updated. ' (Site from CRA). | (b) (4), (b) (6) | 20 Jan 2021 15:24:00 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 20 Jan 2021 15:22:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:22:49 |
| User entered '13 Oct 2020' | Marlee Smith (b) (4) | 10 Nov 2020 18:52:31 |
| | (b) (4) | |

US3722338

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:26:23

[Procedure/Surgery](#)

| Audit | User | Time (GMT) |
|------------------------------|---------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:19:34 |
| User entered 'hernia repair' | Marlee Smith (b) (4) (b) (4) | 10 Nov 2020 18:52:31 |

US3722338

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:26:23

[Indication](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:19:35 |
| User closed query 'Per DM CLR: Indication = Adverse Event, however, the corresponding AE's Other Action Taken does not include 'Concomitant Procedure'. Please reconcile and update necessary eCRF fields, otherwise provide clarification.' (Site from DM). | (b) (4), (b) (6) | 11 Dec 2020 15:29:34 |
| Query 'Per DM CLR: Indication = Adverse Event, however, the corresponding AE's Other Action Taken does not include 'Concomitant Procedure'. Please reconcile and update necessary eCRF fields, otherwise provide clarification.' answered with 'AE Log line 3' (Site from DM). | Marlee Smith (b) (4) (b) (4) | 10 Dec 2020 21:00:45 |
| User opened query 'Per DM CLR: Indication = Adverse Event, however, the corresponding AE's Other Action Taken does not include 'Concomitant Procedure'. Please reconcile and update necessary eCRF fields, otherwise provide clarification.' (Site from DM). | (b) (4), (b) (6) | 02 Dec 2020 15:10:08 |
| User entered 'Adverse Event (AE)' | Marlee Smith (b) (4) (b) (4) | 10 Nov 2020 18:52:31 |

US3722338

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:26:23

[If indication is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:19:38 |
| User entered empty. | Marlee Smith (b) (4) (b) (4) | 10 Nov 2020 18:52:31 |

US3722338

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:26:23

Procedure/Surgery date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 12:32:16 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:35:40 |
| User entered '14 Oct 2020' | Marlee Smith (b) (4) | 19 Jan 2021 15:16:28 |

US3722338

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:26:23

[Procedure/Surgery](#)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 12:32:16 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:36:56 |
| User entered 'coude foley catheter placement' | Marlee Smith (b) (4) | 19 Jan 2021 15:16:28 |

US3722338

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:26:23

[Indication](#)

| Audit | User | Time (GMT) |
|-----------------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 12:32:16 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:35:41 |
| User entered 'Adverse Event (AE)' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:16:28 |

US3722338

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:26:23

If indication is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 12:32:16 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:36:51 |
| User entered empty. | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:16:28 |

US3722338

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:26:23

Procedure/Surgery date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 12:32:19 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User closed query 'Per DM CLR: Please review the Date of this procedure/Surgery, as it is out of the expected timeframe with the AE #6 ACUTE URINARY RETENTION REQUIRING COUDE FOLEY CATHETER (14 OCT 2020-21 OCT 2020). Please review and reconcile date of procedure or clarify as necessary. ' (Site from DM). | (b) (4) (b) (4), (b) (6) | 16 Mar 2021 18:30:59 |
| Query 'Per DM CLR: Please review the Date of this procedure/Surgery, as it is out of the expected timeframe with the AE #6 ACUTE URINARY RETENTION REQUIRING COUDE FOLEY CATHETER (14 OCT 2020-21 OCT 2020). Please review and reconcile date of procedure or clarify as necessary. ' answered with 'original catheter had to be replaced' (Site from DM). | Marlee Smith (b) (4) (b) (4) | 09 Mar 2021 20:40:08 |
| User opened query 'Per DM CLR: Please review the Date of this procedure/Surgery, as it is out of the expected timeframe with the AE #6 ACUTE URINARY RETENTION REQUIRING COUDE FOLEY CATHETER (14 OCT 2020-21 OCT 2020). Please review and reconcile date of procedure or clarify as necessary. ' (Site from DM). | (b) (4), (b) (6) | 26 Feb 2021 09:15:46 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:37:11 |
| User entered '26 Oct 2020' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:16:59 |

US3722338

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:26:23

[Procedure/Surgery](#)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 12:32:19 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:37:13 |
| User entered 'coude foley catheter replacement' | Marlee Smith (b) (4) | 19 Jan 2021 15:16:59 |

US3722338

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:26:23

[Indication](#)

| Audit | User | Time (GMT) |
|-----------------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 12:32:19 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Jan 2021 15:37:15 |
| User entered 'Adverse Event (AE)' | Marlee Smith (b) (4) (b) (4) | 19 Jan 2021 15:16:59 |

US3722338

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:26:23

If indication is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 12:32:19 |
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:37:17 |
| User entered empty. | Marlee Smith (b) (4) | 19 Jan 2021 15:16:59 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[SAEID](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'USA-US083-2020-MRNA-1273-P301000002' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

Serious

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'Yes (Y)' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

Death

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'No (N)' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'No (N)' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'Yes (Y)' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'No (N)' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'No (N)' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'No (N)' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'Luis' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'De La Cruz' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|------------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered '2 Roper Corners Cir' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

Site Address: [City](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'Greenville' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

Site Address: [State](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'SC' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered '29615' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:53:07 |
| User entered 'US' | System | 23 Oct 2020 19:53:03 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|-------------------|--------|----------------------|
| User entered '14' | System | 28 Apr 2021 14:57:11 |
| User entered '13' | System | 19 Apr 2021 13:22:18 |
| User entered '12' | System | 16 Apr 2021 19:10:24 |
| User entered '11' | System | 08 Apr 2021 13:35:28 |
| User entered '10' | System | 02 Apr 2021 16:46:55 |
| User entered '9' | System | 10 Mar 2021 13:31:19 |
| User entered '8' | System | 10 Mar 2021 13:09:30 |
| User entered '7' | System | 09 Mar 2021 15:26:39 |
| User entered '6' | System | 18 Feb 2021 21:53:22 |
| User entered '5' | System | 20 Jan 2021 15:45:07 |
| User entered '4' | System | 13 Jan 2021 17:04:34 |
| User entered '3' | System | 25 Nov 2020 19:12:23 |
| User entered '2' | System | 04 Nov 2020 15:01:44 |
| User entered '1' | System | 23 Oct 2020 19:53:03 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[SAEID](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'USA-US083-2020-MRNA-1273-P301000002' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

Serious

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'Yes (Y)' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'No (N)' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'No (N)' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'Yes (Y)' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'No (N)' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'No (N)' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'No (N)' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'Luis' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'De La Cruz' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

Site Address: [Street](#)

| Audit | User | Time (GMT) |
|------------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered '2 Roper Corners Cir' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

Site Address: [City](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'Greenville' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

Site Address: [State](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'SC' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

Site Address: [Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered '29615' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:53:07 |
| User entered 'US' | System | 23 Oct 2020 19:53:03 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|-------------------|--------|----------------------|
| User entered '14' | System | 28 Apr 2021 14:57:11 |
| User entered '13' | System | 19 Apr 2021 13:22:18 |
| User entered '12' | System | 16 Apr 2021 19:10:24 |
| User entered '11' | System | 08 Apr 2021 13:35:28 |
| User entered '10' | System | 02 Apr 2021 16:46:55 |
| User entered '9' | System | 10 Mar 2021 13:31:19 |
| User entered '8' | System | 10 Mar 2021 13:09:30 |
| User entered '7' | System | 09 Mar 2021 15:26:39 |
| User entered '6' | System | 18 Feb 2021 21:53:22 |
| User entered '5' | System | 20 Jan 2021 15:45:07 |
| User entered '4' | System | 13 Jan 2021 17:04:34 |
| User entered '3' | System | 25 Nov 2020 19:12:23 |
| User entered '2' | System | 04 Nov 2020 15:01:44 |
| User entered '1' | System | 23 Oct 2020 19:53:03 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:26:23

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| User entered '23/Oct/2020 19:53' | System | 23 Oct 2020 19:53:03 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:26:23

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. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:53:07 |
| User entered 'I' | (b) (4), (b) (6) | 23 Oct 2020 19:53:03 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[SAEID](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'USA-US083-2020-MRNA-1273-P301000002' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

Serious

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'Yes (Y)' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

Death

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'No (N)' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'No (N)' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'Yes (Y)' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'No (N)' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'No (N)' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'No (N)' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'Luis' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'De La Cruz' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

Site Address: [Street](#)

| Audit | User | Time (GMT) |
|------------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered '2 Roper Corners Cir' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

Site Address: [City](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'Greenville' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Site Address: State](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'SC' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered '29615' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:53:07 |
| User entered 'US' | System | 23 Oct 2020 19:53:03 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|-------------------|--------|----------------------|
| User entered '14' | System | 28 Apr 2021 14:57:11 |
| User entered '13' | System | 19 Apr 2021 13:22:18 |
| User entered '12' | System | 16 Apr 2021 19:10:24 |
| User entered '11' | System | 08 Apr 2021 13:35:28 |
| User entered '10' | System | 02 Apr 2021 16:46:55 |
| User entered '9' | System | 10 Mar 2021 13:31:19 |
| User entered '8' | System | 10 Mar 2021 13:09:30 |
| User entered '7' | System | 09 Mar 2021 15:26:39 |
| User entered '6' | System | 18 Feb 2021 21:53:22 |
| User entered '5' | System | 20 Jan 2021 15:45:07 |
| User entered '4' | System | 13 Jan 2021 17:04:34 |
| User entered '3' | System | 25 Nov 2020 19:12:23 |
| User entered '2' | System | 04 Nov 2020 15:01:44 |
| User entered '1' | System | 23 Oct 2020 19:53:03 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:26:23

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| User entered '04/Nov/2020 10:01' | System | 04 Nov 2020 15:01:44 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:26:23

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. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 25 Nov 2020 19:12:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| User entered 'I' | (b) (4), (b) (6) | 04 Nov 2020 15:01:44 |
| | | |
| | | |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[SAEID](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'USA-US083-2020-MRNA-1273-P301000002' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

Serious

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'Yes (Y)' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

Death

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'No (N)' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'No (N)' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'Yes (Y)' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'No (N)' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'No (N)' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'No (N)' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'Luis' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'De La Cruz' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

Site Address: [Street](#)

| Audit | User | Time (GMT) |
|------------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered '2 Roper Corners Cir' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

Site Address: [City](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'Greenville' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

Site Address: [State](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'SC' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered '29615' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:53:07 |
| User entered 'US' | System | 23 Oct 2020 19:53:03 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|-------------------|--------|----------------------|
| User entered '14' | System | 28 Apr 2021 14:57:11 |
| User entered '13' | System | 19 Apr 2021 13:22:18 |
| User entered '12' | System | 16 Apr 2021 19:10:24 |
| User entered '11' | System | 08 Apr 2021 13:35:28 |
| User entered '10' | System | 02 Apr 2021 16:46:55 |
| User entered '9' | System | 10 Mar 2021 13:31:19 |
| User entered '8' | System | 10 Mar 2021 13:09:30 |
| User entered '7' | System | 09 Mar 2021 15:26:39 |
| User entered '6' | System | 18 Feb 2021 21:53:22 |
| User entered '5' | System | 20 Jan 2021 15:45:07 |
| User entered '4' | System | 13 Jan 2021 17:04:34 |
| User entered '3' | System | 25 Nov 2020 19:12:23 |
| User entered '2' | System | 04 Nov 2020 15:01:44 |
| User entered '1' | System | 23 Oct 2020 19:53:03 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:26:23

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:15:57 |
| User entered '25/Nov/2020 14:12' | System | 25 Nov 2020 19:12:23 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:26:23

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. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:15:57 |
| Reviewed for Safety. | (b) (4), (b) (6) | 13 Jan 2021 17:04:24 |
| User entered 'I' | (b) (4), (b) (6) | 25 Nov 2020 19:12:23 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[SAEID](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'USA-US083-2020-MRNA-1273-P301000002' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

Serious

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'Yes (Y)' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'No (N)' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'No (N)' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'Yes (Y)' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'No (N)' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'No (N)' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'No (N)' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'Luis' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'De La Cruz' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

Site Address: [Street](#)

| Audit | User | Time (GMT) |
|------------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered '2 Roper Corners Cir' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

Site Address: [City](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'Greenville' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Site Address: State](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'SC' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

Site Address: [Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered '29615' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:53:07 |
| User entered 'US' | System | 23 Oct 2020 19:53:03 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|-------------------|--------|----------------------|
| User entered '14' | System | 28 Apr 2021 14:57:11 |
| User entered '13' | System | 19 Apr 2021 13:22:18 |
| User entered '12' | System | 16 Apr 2021 19:10:24 |
| User entered '11' | System | 08 Apr 2021 13:35:28 |
| User entered '10' | System | 02 Apr 2021 16:46:55 |
| User entered '9' | System | 10 Mar 2021 13:31:19 |
| User entered '8' | System | 10 Mar 2021 13:09:30 |
| User entered '7' | System | 09 Mar 2021 15:26:39 |
| User entered '6' | System | 18 Feb 2021 21:53:22 |
| User entered '5' | System | 20 Jan 2021 15:45:07 |
| User entered '4' | System | 13 Jan 2021 17:04:34 |
| User entered '3' | System | 25 Nov 2020 19:12:23 |
| User entered '2' | System | 04 Nov 2020 15:01:44 |
| User entered '1' | System | 23 Oct 2020 19:53:03 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:26:23

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:15:57 |
| User entered '13/Jan/2021 17:04' | System | 13 Jan 2021 17:04:34 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:26:23

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. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:15:57 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 15:44:53 |
| User entered 'I' | (b) (4), (b) (6) | 13 Jan 2021 17:04:34 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[SAEID](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'USA-US083-2020-MRNA-1273-P301000002' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

Serious

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'Yes (Y)' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'No (N)' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'No (N)' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'Yes (Y)' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'No (N)' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'No (N)' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'No (N)' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'Luis' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'De La Cruz' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

Site Address: [Street](#)

| Audit | User | Time (GMT) |
|------------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered '2 Roper Corners Cir' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

Site Address: [City](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'Greenville' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

Site Address: [State](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'SC' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered '29615' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:53:07 |
| User entered 'US' | System | 23 Oct 2020 19:53:03 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|-------------------|--------|----------------------|
| User entered '14' | System | 28 Apr 2021 14:57:11 |
| User entered '13' | System | 19 Apr 2021 13:22:18 |
| User entered '12' | System | 16 Apr 2021 19:10:24 |
| User entered '11' | System | 08 Apr 2021 13:35:28 |
| User entered '10' | System | 02 Apr 2021 16:46:55 |
| User entered '9' | System | 10 Mar 2021 13:31:19 |
| User entered '8' | System | 10 Mar 2021 13:09:30 |
| User entered '7' | System | 09 Mar 2021 15:26:39 |
| User entered '6' | System | 18 Feb 2021 21:53:22 |
| User entered '5' | System | 20 Jan 2021 15:45:07 |
| User entered '4' | System | 13 Jan 2021 17:04:34 |
| User entered '3' | System | 25 Nov 2020 19:12:23 |
| User entered '2' | System | 04 Nov 2020 15:01:44 |
| User entered '1' | System | 23 Oct 2020 19:53:03 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:26:23

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:15:57 |
| User entered '20/Jan/2021 15:45' | System | 20 Jan 2021 15:45:07 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:26:23

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. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:15:57 |
| Reviewed for Safety. | (b) (4), (b) (6) | 18 Feb 2021 21:51:41 |
| User entered 'I' | (b) (4), (b) (6) | 20 Jan 2021 15:45:07 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[SAEID](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'USA-US083-2020-MRNA-1273-P301000002' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

Serious

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'Yes (Y)' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

Death

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'No (N)' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'No (N)' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'Yes (Y)' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'No (N)' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'No (N)' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'No (N)' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'Luis' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'De La Cruz' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

Site Address: [Street](#)

| Audit | User | Time (GMT) |
|------------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered '2 Roper Corners Cir' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

Site Address: [City](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'Greenville' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

Site Address: [State](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'SC' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered '29615' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:53:07 |
| User entered 'US' | System | 23 Oct 2020 19:53:03 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|-------------------|--------|----------------------|
| User entered '14' | System | 28 Apr 2021 14:57:11 |
| User entered '13' | System | 19 Apr 2021 13:22:18 |
| User entered '12' | System | 16 Apr 2021 19:10:24 |
| User entered '11' | System | 08 Apr 2021 13:35:28 |
| User entered '10' | System | 02 Apr 2021 16:46:55 |
| User entered '9' | System | 10 Mar 2021 13:31:19 |
| User entered '8' | System | 10 Mar 2021 13:09:30 |
| User entered '7' | System | 09 Mar 2021 15:26:39 |
| User entered '6' | System | 18 Feb 2021 21:53:22 |
| User entered '5' | System | 20 Jan 2021 15:45:07 |
| User entered '4' | System | 13 Jan 2021 17:04:34 |
| User entered '3' | System | 25 Nov 2020 19:12:23 |
| User entered '2' | System | 04 Nov 2020 15:01:44 |
| User entered '1' | System | 23 Oct 2020 19:53:03 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 09:26:23

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:15:57 |
| User entered '18/Feb/2021 15:53' | System | 18 Feb 2021 21:53:22 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 09:26:23

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. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:15:57 |
| Reviewed for Safety. | (b) (4), (b) (6) | 18 Feb 2021 21:53:27 |
| User entered 'I' | (b) (4), (b) (6) | 18 Feb 2021 21:53:22 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[SAEID](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'USA-US083-2020-MRNA-1273-P301000002' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

Serious

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'Yes (Y)' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'No (N)' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'No (N)' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'Yes (Y)' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'No (N)' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'No (N)' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'No (N)' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'Luis' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'De La Cruz' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|------------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered '2 Roper Corners Cir' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Site Address: City](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'Greenville' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

Site Address: [State](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'SC' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered '29615' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:53:07 |
| User entered 'US' | System | 23 Oct 2020 19:53:03 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|-------------------|--------|----------------------|
| User entered '14' | System | 28 Apr 2021 14:57:11 |
| User entered '13' | System | 19 Apr 2021 13:22:18 |
| User entered '12' | System | 16 Apr 2021 19:10:24 |
| User entered '11' | System | 08 Apr 2021 13:35:28 |
| User entered '10' | System | 02 Apr 2021 16:46:55 |
| User entered '9' | System | 10 Mar 2021 13:31:19 |
| User entered '8' | System | 10 Mar 2021 13:09:30 |
| User entered '7' | System | 09 Mar 2021 15:26:39 |
| User entered '6' | System | 18 Feb 2021 21:53:22 |
| User entered '5' | System | 20 Jan 2021 15:45:07 |
| User entered '4' | System | 13 Jan 2021 17:04:34 |
| User entered '3' | System | 25 Nov 2020 19:12:23 |
| User entered '2' | System | 04 Nov 2020 15:01:44 |
| User entered '1' | System | 23 Oct 2020 19:53:03 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 09:26:23

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:15:57 |
| User entered '09/Mar/2021 10:26' | System | 09 Mar 2021 15:26:39 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 09:26:23

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. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:15:57 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Apr 2021 16:47:02 |
| User entered 'I' | (b) (4), (b) (6) | 09 Mar 2021 15:26:39 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[SAEID](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'USA-US083-2020-MRNA-1273-P301000002' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

Serious

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'Yes (Y)' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

Death

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'No (N)' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'No (N)' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'Yes (Y)' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'No (N)' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'No (N)' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'No (N)' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'Luis' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'De La Cruz' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

Site Address: [Street](#)

| Audit | User | Time (GMT) |
|------------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered '2 Roper Corners Cir' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

Site Address: [City](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'Greenville' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

Site Address: [State](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'SC' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered '29615' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:53:07 |
| User entered 'US' | System | 23 Oct 2020 19:53:03 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|-------------------|--------|----------------------|
| User entered '14' | System | 28 Apr 2021 14:57:11 |
| User entered '13' | System | 19 Apr 2021 13:22:18 |
| User entered '12' | System | 16 Apr 2021 19:10:24 |
| User entered '11' | System | 08 Apr 2021 13:35:28 |
| User entered '10' | System | 02 Apr 2021 16:46:55 |
| User entered '9' | System | 10 Mar 2021 13:31:19 |
| User entered '8' | System | 10 Mar 2021 13:09:30 |
| User entered '7' | System | 09 Mar 2021 15:26:39 |
| User entered '6' | System | 18 Feb 2021 21:53:22 |
| User entered '5' | System | 20 Jan 2021 15:45:07 |
| User entered '4' | System | 13 Jan 2021 17:04:34 |
| User entered '3' | System | 25 Nov 2020 19:12:23 |
| User entered '2' | System | 04 Nov 2020 15:01:44 |
| User entered '1' | System | 23 Oct 2020 19:53:03 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form (8)

Generated On: 10 Jun 2021 09:26:23

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:15:57 |
| User entered '10/Mar/2021 08:09' | System | 10 Mar 2021 13:09:30 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form (8)

Generated On: 10 Jun 2021 09:26:23

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. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:15:57 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Apr 2021 16:47:02 |
| User entered 'I' | (b) (4), (b) (6) | 10 Mar 2021 13:09:30 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[SAEID](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'USA-US083-2020-MRNA-1273-P301000002' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

Serious

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'Yes (Y)' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

Death

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'No (N)' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'No (N)' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'Yes (Y)' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'No (N)' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'No (N)' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'No (N)' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'Luis' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'De La Cruz' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

Site Address: [Street](#)

| Audit | User | Time (GMT) |
|------------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered '2 Roper Corners Cir' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

Site Address: [City](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'Greenville' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

Site Address: State

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'SC' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered '29615' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:53:07 |
| User entered 'US' | System | 23 Oct 2020 19:53:03 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|-------------------|--------|----------------------|
| User entered '14' | System | 28 Apr 2021 14:57:11 |
| User entered '13' | System | 19 Apr 2021 13:22:18 |
| User entered '12' | System | 16 Apr 2021 19:10:24 |
| User entered '11' | System | 08 Apr 2021 13:35:28 |
| User entered '10' | System | 02 Apr 2021 16:46:55 |
| User entered '9' | System | 10 Mar 2021 13:31:19 |
| User entered '8' | System | 10 Mar 2021 13:09:30 |
| User entered '7' | System | 09 Mar 2021 15:26:39 |
| User entered '6' | System | 18 Feb 2021 21:53:22 |
| User entered '5' | System | 20 Jan 2021 15:45:07 |
| User entered '4' | System | 13 Jan 2021 17:04:34 |
| User entered '3' | System | 25 Nov 2020 19:12:23 |
| User entered '2' | System | 04 Nov 2020 15:01:44 |
| User entered '1' | System | 23 Oct 2020 19:53:03 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form (9)

Generated On: 10 Jun 2021 09:26:23

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:15:57 |
| User entered '10/Mar/2021 08:31' | System | 10 Mar 2021 13:31:19 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form (9)

Generated On: 10 Jun 2021 09:26:23

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. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:15:57 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Apr 2021 16:47:02 |
| User entered 'I' | (b) (4), (b) (6) | 10 Mar 2021 13:31:19 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[SAEID](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'USA-US083-2020-MRNA-1273-P301000002' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

Serious

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'Yes (Y)' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'No (N)' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'No (N)' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'Yes (Y)' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'No (N)' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'No (N)' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'No (N)' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'Luis' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'De La Cruz' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

Site Address: [Street](#)

| Audit | User | Time (GMT) |
|------------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered '2 Roper Corners Cir' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

Site Address: [City](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'Greenville' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

Site Address: [State](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'SC' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered '29615' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:53:07 |
| User entered 'US' | System | 23 Oct 2020 19:53:03 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|-------------------|--------|----------------------|
| User entered '14' | System | 28 Apr 2021 14:57:11 |
| User entered '13' | System | 19 Apr 2021 13:22:18 |
| User entered '12' | System | 16 Apr 2021 19:10:24 |
| User entered '11' | System | 08 Apr 2021 13:35:28 |
| User entered '10' | System | 02 Apr 2021 16:46:55 |
| User entered '9' | System | 10 Mar 2021 13:31:19 |
| User entered '8' | System | 10 Mar 2021 13:09:30 |
| User entered '7' | System | 09 Mar 2021 15:26:39 |
| User entered '6' | System | 18 Feb 2021 21:53:22 |
| User entered '5' | System | 20 Jan 2021 15:45:07 |
| User entered '4' | System | 13 Jan 2021 17:04:34 |
| User entered '3' | System | 25 Nov 2020 19:12:23 |
| User entered '2' | System | 04 Nov 2020 15:01:44 |
| User entered '1' | System | 23 Oct 2020 19:53:03 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form (10)

Generated On: 10 Jun 2021 09:26:23

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:15:57 |
| User entered '02/Apr/2021 12:46' | System | 02 Apr 2021 16:46:55 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form (10)

Generated On: 10 Jun 2021 09:26:23

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. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:15:57 |
| Reviewed for Safety. | (b) (4), (b) (6) | 02 Apr 2021 16:47:02 |
| User entered 'I' | (b) (4), (b) (6) | 02 Apr 2021 16:46:55 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[SAEID](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'USA-US083-2020-MRNA-1273-P301000002' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

Serious

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'Yes (Y)' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'No (N)' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'No (N)' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'Yes (Y)' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'No (N)' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'No (N)' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'No (N)' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'Luis' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'De La Cruz' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

Site Address: [Street](#)

| Audit | User | Time (GMT) |
|------------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered '2 Roper Corners Cir' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

Site Address: [City](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'Greenville' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Site Address: State](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'SC' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered '29615' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:53:07 |
| User entered 'US' | System | 23 Oct 2020 19:53:03 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|-------------------|--------|----------------------|
| User entered '14' | System | 28 Apr 2021 14:57:11 |
| User entered '13' | System | 19 Apr 2021 13:22:18 |
| User entered '12' | System | 16 Apr 2021 19:10:24 |
| User entered '11' | System | 08 Apr 2021 13:35:28 |
| User entered '10' | System | 02 Apr 2021 16:46:55 |
| User entered '9' | System | 10 Mar 2021 13:31:19 |
| User entered '8' | System | 10 Mar 2021 13:09:30 |
| User entered '7' | System | 09 Mar 2021 15:26:39 |
| User entered '6' | System | 18 Feb 2021 21:53:22 |
| User entered '5' | System | 20 Jan 2021 15:45:07 |
| User entered '4' | System | 13 Jan 2021 17:04:34 |
| User entered '3' | System | 25 Nov 2020 19:12:23 |
| User entered '2' | System | 04 Nov 2020 15:01:44 |
| User entered '1' | System | 23 Oct 2020 19:53:03 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form (11)

Generated On: 10 Jun 2021 09:26:23

Date of submission (Pre-filled from custom function)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:15:57 |
| User entered '08/Apr/2021 08:35' | System | 08 Apr 2021 13:35:28 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form (11)

Generated On: 10 Jun 2021 09:26:23

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. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Apr 2021 19:10:13 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 14:15:57 |
| | | |
| User entered 'I' | (b) (4), (b) (6) | 08 Apr 2021 13:35:28 |
| | | |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[SAEID](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'USA-US083-2020-MRNA-1273-P301000002' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

Serious

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'Yes (Y)' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

Death

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'No (N)' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'No (N)' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'Yes (Y)' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'No (N)' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'No (N)' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'No (N)' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'Luis' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'De La Cruz' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

Site Address: [Street](#)

| Audit | User | Time (GMT) |
|------------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered '2 Roper Corners Cir' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

Site Address: [City](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'Greenville' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Site Address: State](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'SC' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered '29615' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:53:07 |
| User entered 'US' | System | 23 Oct 2020 19:53:03 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|-------------------|--------|----------------------|
| User entered '14' | System | 28 Apr 2021 14:57:11 |
| User entered '13' | System | 19 Apr 2021 13:22:18 |
| User entered '12' | System | 16 Apr 2021 19:10:24 |
| User entered '11' | System | 08 Apr 2021 13:35:28 |
| User entered '10' | System | 02 Apr 2021 16:46:55 |
| User entered '9' | System | 10 Mar 2021 13:31:19 |
| User entered '8' | System | 10 Mar 2021 13:09:30 |
| User entered '7' | System | 09 Mar 2021 15:26:39 |
| User entered '6' | System | 18 Feb 2021 21:53:22 |
| User entered '5' | System | 20 Jan 2021 15:45:07 |
| User entered '4' | System | 13 Jan 2021 17:04:34 |
| User entered '3' | System | 25 Nov 2020 19:12:23 |
| User entered '2' | System | 04 Nov 2020 15:01:44 |
| User entered '1' | System | 23 Oct 2020 19:53:03 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form (12)

Generated On: 10 Jun 2021 09:26:23

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 26 Apr 2021 16:25:15 |
| User entered '16/Apr/2021 14:10' | System | 16 Apr 2021 19:10:24 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form (12)

Generated On: 10 Jun 2021 09:26:23

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. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 26 Apr 2021 16:25:15 |
| Reviewed for Safety. | (b) (4), (b) (6) | 19 Apr 2021 13:22:03 |
| User entered 'I' | (b) (4), (b) (6) | 16 Apr 2021 19:10:24 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[SAEID](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'USA-US083-2020-MRNA-1273-P301000002' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

Serious

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'Yes (Y)' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

Death

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'No (N)' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'No (N)' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'Yes (Y)' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'No (N)' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'No (N)' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'No (N)' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'Luis' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'De La Cruz' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

Site Address: [Street](#)

| Audit | User | Time (GMT) |
|------------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered '2 Roper Corners Cir' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

Site Address: [City](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'Greenville' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Site Address: State](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'SC' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

Site Address: [Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered '29615' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:53:07 |
| User entered 'US' | System | 23 Oct 2020 19:53:03 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|-------------------|--------|----------------------|
| User entered '14' | System | 28 Apr 2021 14:57:11 |
| User entered '13' | System | 19 Apr 2021 13:22:18 |
| User entered '12' | System | 16 Apr 2021 19:10:24 |
| User entered '11' | System | 08 Apr 2021 13:35:28 |
| User entered '10' | System | 02 Apr 2021 16:46:55 |
| User entered '9' | System | 10 Mar 2021 13:31:19 |
| User entered '8' | System | 10 Mar 2021 13:09:30 |
| User entered '7' | System | 09 Mar 2021 15:26:39 |
| User entered '6' | System | 18 Feb 2021 21:53:22 |
| User entered '5' | System | 20 Jan 2021 15:45:07 |
| User entered '4' | System | 13 Jan 2021 17:04:34 |
| User entered '3' | System | 25 Nov 2020 19:12:23 |
| User entered '2' | System | 04 Nov 2020 15:01:44 |
| User entered '1' | System | 23 Oct 2020 19:53:03 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form (13)

Generated On: 10 Jun 2021 09:26:23

Date of submission (Pre-filled from custom function)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 26 Apr 2021 16:25:15 |
| User entered '19/Apr/2021 13:22' | System | 19 Apr 2021 13:22:18 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form (13)

Generated On: 10 Jun 2021 09:26:23

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. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 26 Apr 2021 16:25:15 |
| User entered 'I' | (b) (4), (b) (6) | 19 Apr 2021 13:22:18 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[SAEID](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'USA-US083-2020-MRNA-1273-P301000002' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

Serious

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'Yes (Y)' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'No (N)' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'No (N)' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'Yes (Y)' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'No (N)' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'No (N)' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'No (N)' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'Luis' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'De La Cruz' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

Site Address: [Street](#)

| Audit | User | Time (GMT) |
|------------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered '2 Roper Corners Cir' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

Site Address: [City](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'Greenville' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

Site Address: State

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered 'SC' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:52:56 |
| User entered '29615' | System | 23 Oct 2020 19:50:37 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 01:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 19:53:07 |
| User entered 'US' | System | 23 Oct 2020 19:53:03 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|-------------------|--------|----------------------|
| User entered '14' | System | 28 Apr 2021 14:57:11 |
| User entered '13' | System | 19 Apr 2021 13:22:18 |
| User entered '12' | System | 16 Apr 2021 19:10:24 |
| User entered '11' | System | 08 Apr 2021 13:35:28 |
| User entered '10' | System | 02 Apr 2021 16:46:55 |
| User entered '9' | System | 10 Mar 2021 13:31:19 |
| User entered '8' | System | 10 Mar 2021 13:09:30 |
| User entered '7' | System | 09 Mar 2021 15:26:39 |
| User entered '6' | System | 18 Feb 2021 21:53:22 |
| User entered '5' | System | 20 Jan 2021 15:45:07 |
| User entered '4' | System | 13 Jan 2021 17:04:34 |
| User entered '3' | System | 25 Nov 2020 19:12:23 |
| User entered '2' | System | 04 Nov 2020 15:01:44 |
| User entered '1' | System | 23 Oct 2020 19:53:03 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form (14)

Generated On: 10 Jun 2021 09:26:23

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|-------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered '28/Apr/2021 07:57' | (b) (4) System | 28 Apr 2021 14:57:11 |

US3722338

Folder: SAE USA-US083-2020-MRNA-1273-P301000002

Form: Safety Report Form (14)

Generated On: 10 Jun 2021 09:26:23

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. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| User entered 'I' | (b) (4) (b) (4), (b) (6) | 28 Apr 2021 14:57:11 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[SAEID](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered 'USA-US083-2021-MRNA-1273-P301000003' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

Serious

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered 'Yes (Y)' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

Death

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered 'No (N)' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered 'No (N)' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered 'Yes (Y)' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered 'No (N)' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered 'No (N)' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered 'No (N)' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered 'Luis' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered 'De La Cruz' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

Site Address: [Street](#)

| Audit | User | Time (GMT) |
|------------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered '2 Roper Corners Cir' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

Site Address: [City](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered 'Greenville' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

Site Address: State

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered 'SC' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered '29615' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 18 Feb 2021 21:26:30 |
| User entered 'US' | System | 20 Jan 2021 17:02:30 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '7' | System | 16 Apr 2021 20:18:21 |
| User entered '6' | System | 16 Apr 2021 13:46:33 |
| User entered '5' | System | 08 Apr 2021 13:35:51 |
| User entered '4' | System | 10 Mar 2021 15:51:06 |
| User entered '3' | System | 09 Mar 2021 15:45:11 |
| User entered '2' | System | 18 Feb 2021 21:26:46 |
| User entered '1' | System | 20 Jan 2021 17:02:30 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[SAEID](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered 'USA-US083-2021-MRNA-1273-P301000003' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

Serious

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered 'Yes (Y)' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

Death

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered 'No (N)' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered 'No (N)' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered 'Yes (Y)' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered 'No (N)' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered 'No (N)' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered 'No (N)' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered 'Luis' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered 'De La Cruz' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|------------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered '2 Roper Corners Cir' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Site Address: City](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered 'Greenville' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

Site Address: [State](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered 'SC' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

Site Address: [Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered '29615' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 18 Feb 2021 21:26:30 |
| User entered 'US' | System | 20 Jan 2021 17:02:30 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '7' | System | 16 Apr 2021 20:18:21 |
| User entered '6' | System | 16 Apr 2021 13:46:33 |
| User entered '5' | System | 08 Apr 2021 13:35:51 |
| User entered '4' | System | 10 Mar 2021 15:51:06 |
| User entered '3' | System | 09 Mar 2021 15:45:11 |
| User entered '2' | System | 18 Feb 2021 21:26:46 |
| User entered '1' | System | 20 Jan 2021 17:02:30 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:26:23

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| User entered '20/Jan/2021 17:02' | System | 20 Jan 2021 17:02:30 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:26:23

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. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 18 Feb 2021 21:26:30 |
| User entered 'I' | (b) (4), (b) (6) | 20 Jan 2021 17:02:30 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[SAEID](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered 'USA-US083-2021-MRNA-1273-P301000003' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

Serious

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered 'Yes (Y)' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

Death

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered 'No (N)' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered 'No (N)' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered 'Yes (Y)' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered 'No (N)' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered 'No (N)' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered 'No (N)' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered 'Luis' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered 'De La Cruz' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

Site Address: [Street](#)

| Audit | User | Time (GMT) |
|------------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered '2 Roper Corners Cir' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

Site Address: [City](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered 'Greenville' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

Site Address: State

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered 'SC' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered '29615' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 18 Feb 2021 21:26:30 |
| User entered 'US' | System | 20 Jan 2021 17:02:30 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '7' | System | 16 Apr 2021 20:18:21 |
| User entered '6' | System | 16 Apr 2021 13:46:33 |
| User entered '5' | System | 08 Apr 2021 13:35:51 |
| User entered '4' | System | 10 Mar 2021 15:51:06 |
| User entered '3' | System | 09 Mar 2021 15:45:11 |
| User entered '2' | System | 18 Feb 2021 21:26:46 |
| User entered '1' | System | 20 Jan 2021 17:02:30 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:26:23

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| User entered '18/Feb/2021 16:26' | System | 18 Feb 2021 21:26:46 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:26:23

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. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 09 Mar 2021 15:44:49 |
| User entered 'I' | (b) (4), (b) (6) | 18 Feb 2021 21:26:46 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[SAEID](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered 'USA-US083-2021-MRNA-1273-P301000003' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

Serious

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered 'Yes (Y)' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered 'No (N)' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered 'No (N)' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered 'Yes (Y)' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered 'No (N)' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered 'No (N)' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered 'No (N)' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered 'Luis' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered 'De La Cruz' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

Site Address: [Street](#)

| Audit | User | Time (GMT) |
|------------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered '2 Roper Corners Cir' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Site Address: City](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered 'Greenville' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

Site Address: [State](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered 'SC' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

Site Address: [Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered '29615' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 18 Feb 2021 21:26:30 |
| User entered 'US' | System | 20 Jan 2021 17:02:30 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '7' | System | 16 Apr 2021 20:18:21 |
| User entered '6' | System | 16 Apr 2021 13:46:33 |
| User entered '5' | System | 08 Apr 2021 13:35:51 |
| User entered '4' | System | 10 Mar 2021 15:51:06 |
| User entered '3' | System | 09 Mar 2021 15:45:11 |
| User entered '2' | System | 18 Feb 2021 21:26:46 |
| User entered '1' | System | 20 Jan 2021 17:02:30 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:26:23

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| User entered '09/Mar/2021 10:45' | System | 09 Mar 2021 15:45:11 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:26:23

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. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 10 Mar 2021 15:50:41 |
| User entered 'I' | (b) (4), (b) (6) | 09 Mar 2021 15:45:11 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[SAEID](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered 'USA-US083-2021-MRNA-1273-P301000003' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

Serious

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered 'Yes (Y)' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

Death

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered 'No (N)' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered 'No (N)' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered 'Yes (Y)' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered 'No (N)' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered 'No (N)' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered 'No (N)' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered 'Luis' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered 'De La Cruz' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|------------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered '2 Roper Corners Cir' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

Site Address: [City](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered 'Greenville' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

Site Address: [State](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered 'SC' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered '29615' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 18 Feb 2021 21:26:30 |
| User entered 'US' | System | 20 Jan 2021 17:02:30 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '7' | System | 16 Apr 2021 20:18:21 |
| User entered '6' | System | 16 Apr 2021 13:46:33 |
| User entered '5' | System | 08 Apr 2021 13:35:51 |
| User entered '4' | System | 10 Mar 2021 15:51:06 |
| User entered '3' | System | 09 Mar 2021 15:45:11 |
| User entered '2' | System | 18 Feb 2021 21:26:46 |
| User entered '1' | System | 20 Jan 2021 17:02:30 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:26:23

Date of submission (Pre-filled from custom function)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| User entered '10/Mar/2021 09:51' | System | 10 Mar 2021 15:51:06 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:26:23

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. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 08 Apr 2021 13:35:37 |
| User entered 'I' | (b) (4), (b) (6) | 10 Mar 2021 15:51:06 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[SAEID](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered 'USA-US083-2021-MRNA-1273-P301000003' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

Serious

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered 'Yes (Y)' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

Death

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered 'No (N)' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered 'No (N)' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered 'Yes (Y)' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered 'No (N)' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered 'No (N)' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered 'No (N)' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered 'Luis' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered 'De La Cruz' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

Site Address: [Street](#)

| Audit | User | Time (GMT) |
|------------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered '2 Roper Corners Cir' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

Site Address: [City](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered 'Greenville' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

Site Address: [State](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered 'SC' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered '29615' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 18 Feb 2021 21:26:30 |
| User entered 'US' | System | 20 Jan 2021 17:02:30 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '7' | System | 16 Apr 2021 20:18:21 |
| User entered '6' | System | 16 Apr 2021 13:46:33 |
| User entered '5' | System | 08 Apr 2021 13:35:51 |
| User entered '4' | System | 10 Mar 2021 15:51:06 |
| User entered '3' | System | 09 Mar 2021 15:45:11 |
| User entered '2' | System | 18 Feb 2021 21:26:46 |
| User entered '1' | System | 20 Jan 2021 17:02:30 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:26:23

Date of submission (Pre-filled from custom function)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| User entered '08/Apr/2021 08:35' | System | 08 Apr 2021 13:35:51 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:26:23

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. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Apr 2021 13:45:18 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| | | |
| User entered 'I' | (b) (4), (b) (6) | 08 Apr 2021 13:35:51 |
| | | |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[SAEID](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered 'USA-US083-2021-MRNA-1273-P301000003' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

Serious

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered 'Yes (Y)' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered 'No (N)' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered 'No (N)' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered 'Yes (Y)' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered 'No (N)' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered 'No (N)' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered 'No (N)' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered 'Luis' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered 'De La Cruz' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

Site Address: [Street](#)

| Audit | User | Time (GMT) |
|------------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered '2 Roper Corners Cir' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

Site Address: [City](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered 'Greenville' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Site Address: State](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered 'SC' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

Site Address: [Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered '29615' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 18 Feb 2021 21:26:30 |
| User entered 'US' | System | 20 Jan 2021 17:02:30 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '7' | System | 16 Apr 2021 20:18:21 |
| User entered '6' | System | 16 Apr 2021 13:46:33 |
| User entered '5' | System | 08 Apr 2021 13:35:51 |
| User entered '4' | System | 10 Mar 2021 15:51:06 |
| User entered '3' | System | 09 Mar 2021 15:45:11 |
| User entered '2' | System | 18 Feb 2021 21:26:46 |
| User entered '1' | System | 20 Jan 2021 17:02:30 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 09:26:23

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 26 Apr 2021 16:25:27 |
| User entered '16/Apr/2021 09:46' | System | 16 Apr 2021 13:46:33 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 09:26:23

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. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 26 Apr 2021 16:25:27 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Apr 2021 20:18:04 |
| User entered 'I' | (b) (4), (b) (6) | 16 Apr 2021 13:46:33 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[SAEID](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered 'USA-US083-2021-MRNA-1273-P301000003' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

Serious

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered 'Yes (Y)' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

Death

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered 'No (N)' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered 'No (N)' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered 'Yes (Y)' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered 'No (N)' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered 'No (N)' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered 'No (N)' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered 'Luis' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered 'De La Cruz' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

Site Address: [Street](#)

| Audit | User | Time (GMT) |
|------------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered '2 Roper Corners Cir' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

Site Address: [City](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered 'Greenville' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

Site Address: [State](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered 'SC' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

Site Address: [Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 20 Jan 2021 17:02:21 |
| User entered '29615' | System | 20 Jan 2021 17:01:27 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 08 Apr 2021 14:16:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 18 Feb 2021 21:26:30 |
| User entered 'US' | System | 20 Jan 2021 17:02:30 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:23

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '7' | System | 16 Apr 2021 20:18:21 |
| User entered '6' | System | 16 Apr 2021 13:46:33 |
| User entered '5' | System | 08 Apr 2021 13:35:51 |
| User entered '4' | System | 10 Mar 2021 15:51:06 |
| User entered '3' | System | 09 Mar 2021 15:45:11 |
| User entered '2' | System | 18 Feb 2021 21:26:46 |
| User entered '1' | System | 20 Jan 2021 17:02:30 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 09:26:23

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 26 Apr 2021 16:25:27 |
| User entered '16/Apr/2021 20:18' | System | 16 Apr 2021 20:18:21 |

US3722338

Folder: SAE USA-US083-2021-MRNA-1273-P301000003

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 09:26:23

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. | Luis De La Cruz (b) (4) | 28 Apr 2021 21:56:16 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 26 Apr 2021 16:25:27 |
| User entered 'I' | (b) (4), (b) (6) | 16 Apr 2021 20:18:21 |